



State of Tennessee

Health Services and Development Agency

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

Date: October 9, 2014

To: HSDA Members

From: Melanie M. Hill, Executive Director

Re: CONSENT CALENDAR JUSTIFICATION
CN1408-036– Sumner Regional Medical Center

As permitted by Statute and further explained by Agency Rule later in this memo, I have placed this application on the consent calendar based upon my determination that the application appears to meet the established criteria for granting a certificate of need. Need, economic feasibility and contribution to the orderly development of health care appear to have been demonstrated as detailed below. If Agency Members determine that the criteria have been met, a member may move to approve the application by adopting the criteria set forth in this justification or develop another motion for approval that addresses each of the three criteria required for approval of a certificate of need.

At the time the application entered the review cycle on September 2, 2014, it was not opposed. If the application is opposed prior to it being heard, it will be moved to the bottom of the regular October agenda and the applicant will make a full presentation.

Summary—

This application is for the relocation of the existing linear accelerator service from the main campus of Sumner Regional Medical Center to the outpatient campus, which is a distance of approximately 6.9 miles. A certificate of need is required because the change in location of a health care service or the relocation of major medical equipment triggers a certificate of need requirement (TCA 68-11-1607 (a) (5)). A linear accelerator qualifies as both a health care service and major medical equipment. Since the project involves only the replacement of an existing 18- year old linear accelerator, Agency approval is not required to acquire the new linear accelerator because the replacement/upgrade of existing equipment which improves the quality or cost effectiveness is exempt provided the applicant file the proper notice at the time of the replacement.

Sumner Regional Medical Center is located at 555 Hartsville Pike in Gallatin. The outpatient campus is located on 24.6 acres at 225 Big Station Camp Road in Gallatin. The existing 95,998 SF 2-story building will be modified to house the service. The total project includes 10,720 SF, which includes building out 9,150 SF of shelled space and constructing 1,570 SF of new space to house the linear accelerator vault. The build-out space includes patient waiting area, business and doctor's offices, exam rooms, CT/simulator room, and other support space.

The applicant indicates the relocation is needed because it will provide easier access to services and alleviate traffic, parking, congestion, and wayfinding issues at the main campus. The outpatient campus, which is located off Vietnam Veterans Parkway, provides easy access, improved parking, and will provide covered entrances to the building.

Life Point Hospitals, Inc. the parent organization of Sumner Regional, has committed to funding the project.

Imaging and rehabilitation services are currently provided at the outpatient campus. The approval of this application will relocate another service that is primarily an outpatient service to a more accessible location. This is especially important when consideration is given to the volume and length of the typical treatment schedule for radiation therapy (5 days a week for 5-6 weeks)

Sumner Regional is licensed by the TN Department of Health and accredited by The Joint Commission as a 155-bed general hospital providing acute, rehabilitation, and psychiatric services. It participates in all TennCare MCOs in the service area.

Please refer to the application packet for more detailed information.

Executive Director Justification -

I recommend approval based upon my belief the general criteria for a certificate of need have been met.

Need- The relocation will provide easier access to the only radiation services provided in Sumner and Macon Counties, which is especially important given the high cancer rates in these counties.

Economic Feasibility- The project will be funded by cash reserves of the parent company and is projected to have positive net operating income less capital expenditures in Year 1.

Contribution to the Orderly Development of Health Care- This project does not duplicate existing services nor does it increase the cost associated with it. It simply relocates an existing service to a more convenient, consumer friendly location, which is extremely important given the volume and length of treatment times in radiation therapy.

Statutory Citation -TCA 68-11-1608. Review of applications -- Report

(d) The executive director may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must

not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

Rules of the Health Services and Development Agency-- 0720-10-.05 CONSENT CALENDAR

- (1) Each monthly meeting's agenda will be available for both a consent calendar and a regular calendar.
- (2) In order to be placed on the consent calendar, the application must not be opposed by anyone having legal standing to oppose the application, and the executive director must determine that the application appears to meet the established criteria for granting a certificate of need. Public notice of all applications intended to be placed on the consent calendar will be given.
- (3) As to all applications which are placed on the consent calendar, the reviewing agency shall file its official report with The Agency within thirty (30) days of the beginning of the applicable review cycle.
- (4) If opposition by anyone having legal standing to oppose the application is stated in writing prior to the application being formally considered by The Agency, it will be taken off the consent calendar and placed on the next regular agenda. Any member of The Agency may state opposition to the application being heard on the consent calendar, and if reasonable grounds for such opposition are given, the application will be removed from the consent calendar and placed on the next regular agenda.
 - (a) For purposes of this rule, the "next regular agenda" means the next regular calendar to be considered at the same monthly meeting.
- (5) Any application which remains on the consent calendar will be individually considered and voted upon by The Agency.

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HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
OCTOBER 22, 2014
APPLICATION SUMMARY

NAME OF PROJECT: Sumner Regional Medical Center

PROJECT NUMBER: CN1408-036

ADDRESS: 225 Big Station Camp Road
Gallatin (Sumner County), TN 37066

LEGAL OWNER: Sumner Regional Medical Center, LLC
330 Seven Springs Way
Brentwood, TN 37027

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Michael Herman
(615) 328-6695

DATE FILED: August 15, 2014

PROJECT COST: \$10,512,421.00

FINANCING: Cash Reserves

PURPOSE FOR FILING: Relocation of existing linear accelerator from main hospital campus to outpatient campus and operation of radiation therapy service at that location under hospital license

DESCRIPTION:

Sumner Regional Medical Center (SRMC), a 155 licensed bed acute care hospital, is seeking approval to relocate its existing radiation therapy service from the main hospital campus to its outpatient campus, a distance of approximately 6.9 miles between locations in Gallatin (Sumner County), Tennessee. As part of the project, the applicant plans to replace its existing unit acquired in 1996 with a new unit with better technology and will renovate space in the existing outpatient building to house the service. The project does not involve the initiation of a new service, the acquisition of major medical equipment or a change in the applicant's existing service area. The applicant has been placed under CONSENT CALENDAR REVIEW in accordance with TCA §68-11-1608(d) and Agency Rule 0720-10-.05.

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SPECIFIC CRITERIA AND STANDARDS REVIEW:

CONSTRUCTION, RENOVATION, EXPANSION, AND REPLACEMENT OF HEALTH CARE INSTITUTIONS

1. Any project that includes the addition of beds, services, or medical equipment will be reviewed under the standards for those specific activities.

The applicant seeks approval to relocate an existing linear accelerator unit to its outpatient campus.

It appears that this criterion is not applicable.

2. For relocation or replacement of an existing licensed health care institution:
 - a. The applicant should provide plans which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.

No plans were identified or addressed for renovation as the major focus of the project is goal is to improve convenience and accessibility by relocating SRMC's radiation therapy service away from the main campus to its existing outpatient campus. No alternatives were considered as the Sumner Station location already exists and is cost effective.

It appears that the applicant meets this criterion.

- b. The applicant should demonstrate that there is an acceptable existing or projected future demand for the proposed project.

The applicant documented the utilization of the existing service at an average of approximately 4,200 procedures per year from 2011 to 2013. Several factors were identified that may increase demand for the existing service such as improved access by area residents to the new location on SRMC's outpatient campus, a higher incidence of cancer in the 2 county service area than the statewide average, reduction of outmigration to other providers due to better technology, and support for the project by the area's largest oncology practice.

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It appears that the applicant meets this criterion.

3. For renovation or expansions of an existing licensed health care institution:

- a. The applicant should demonstrate that there is an acceptable existing demand for the proposed project.
- b. The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion.

The project involves relocation of the applicant's radiation therapy service to its existing outpatient campus where it will continue to be operated under the hospital license.

The above criteria are not applicable.

Staff Summary

The following information is a summary of the original application and all supplemental responses. Any staff comments or notes, if applicable, will be in bold italics.

Sumner Regional Medical Center operates a 155 licensed bed hospital and an outpatient campus in Sumner County under the same license. The applicant seeks approval under **Consent Calendar Review** to relocate its existing fixed/stationary linear accelerator service from the main hospital campus at 555 Hartsville Pike, Gallatin (Sumner County), TN to an existing building on the hospital's 24.6 acre outpatient campus at 225 Big Station Camp Boulevard, Gallatin (Sumner County), TN, a distance of approximately 6.9 miles. As part of the project, the applicant will renovate approximately 9,150 square feet of space for the linear accelerator service and add 1,570 SF of new construction to house the unit's vault in the existing 95,998 SF 2-story outpatient facility. SRMC will also replace its existing fixed linear accelerator that has been in service since 1996 with a new state of the art Varian TrueBeam unit with CT simulator. The hours and days of operation will not change as a result of the proposed relocation to the applicant's outpatient campus.

The current total licensed bed complement consists of 155 licensed hospital beds as follows: 90 medical, 15 obstetrical, 18 ICU/CCU, 20 rehabilitation and 12 inpatient geriatric psychiatric beds. Although all of the licensed beds are presently staffed, review of the Joint Annual Report revealed that 133 beds were staffed in calendar year (CY) 2013. Based on 33,900 total inpatient days, SRMC's licensed and staffed hospital bed occupancy was 60% and 70%, respectively,

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during the period. According to the Department of Health and pertaining to the Joint Annual Reports, the following defines the two bed categories:

Licensed Beds- The maximum number of beds authorized by the appropriate state licensing (certifying) agency or regulated by a federal agency. This figure is broken down into adult and pediatric beds and licensed bassinets (neonatal intensive or intermediate care bassinets).

Staffed Beds-The total number of adult and pediatric beds set up, staffed and in use at the end of the reporting period. This number should be less than or equal to the number of licensed beds.

Ownership

- Sumner Regional Medical Center (STMC) is owned by LifePoint Hospitals, Inc.
- Lifepoint operates a total of 63 hospitals in 20 states, including 10 hospitals in Tennessee.
- Attachment A.4 contains an organizational chart and a list of facilities owned by LifePoint Hospitals, Inc.

Facility Information

- Only provider of radiation therapy service in Sumner and Macon Counties.
- Current unit has been operated at SRMC for approximately 18 years. It provides treatments using external beam radiation therapy (EBRT), 3-D conformal radiation therapy (3-D CRT) and Intensity Modulated Radiation Therapy (IMRT).
- Proposed site of applicant's radiation therapy service is a 26 acre outpatient campus in use since 2007, located approximately 6.9 miles from hospital main campus.
- Campus contains existing 95,998 square foot 2-story building constructed in 2007.
- Current occupants on SRMC's outpatient campus (imaging, rehabilitation and sports medicine) utilize approximately 21,660 square feet or 23% of the total building space.
- SRMC is modernizing its oncology program and has pending application for initiation of PET/CT service, CN1409-041 that will be heard at the December 17, 2014 Agency meeting.
- Hospital will provide transportation of inpatients to the Sumner Station outpatient campus by ambulance.
- A floor plan drawing of the proposed site is included as Attachment B.IV.

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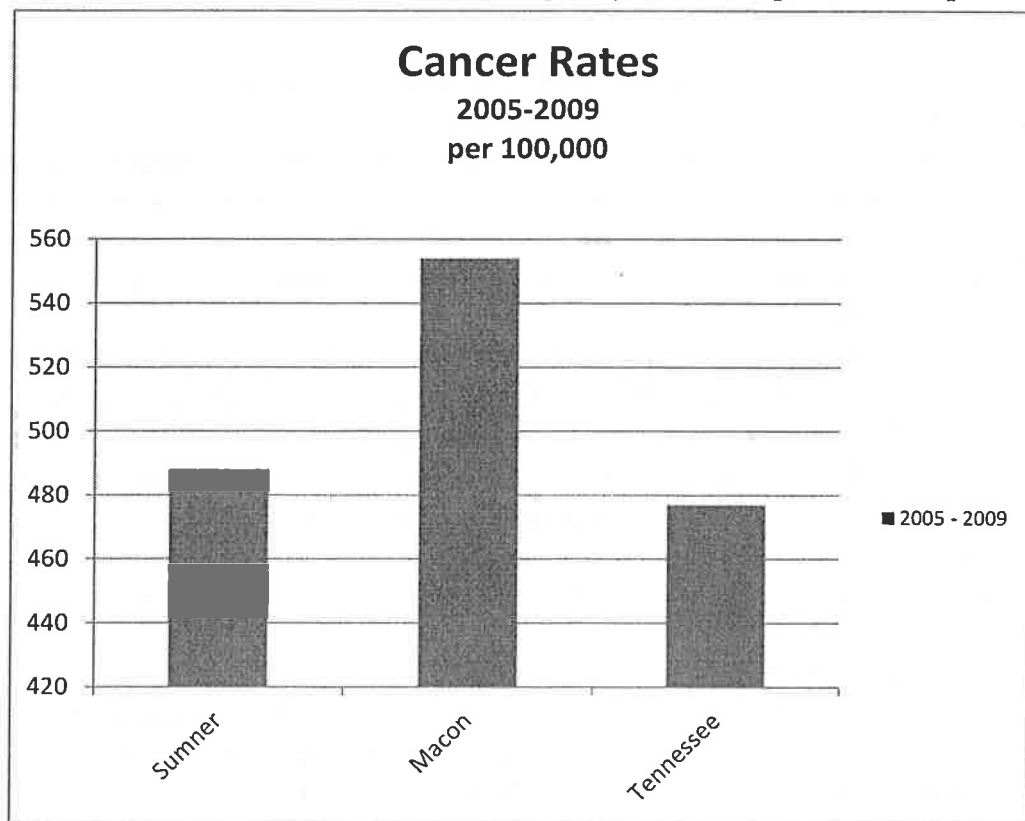
Linear Accelerator Equipment

- The replacement Varian TrueBeam unit includes all of the existing unit's features.
- New technology upgrades include real time diagnostic imaging using an On-Board Imager (OBI), image guided targeting and Stereotactic Radiosurgery (SRS). *Note: please see page 9 application and pages 4 and 5 of the 8/26/14 supplemental response for full description of the new replacement unit.*
- Replacement unit allows the physician and oncology teams more options to treat patients with better outcomes, shorter treatment sessions, improved targeting accuracy, and less side effects.

Project Need

The applicant identified the need for the proposed relocation of SRMC's radiation therapy service and replacement of its existing linear accelerator in the application. Additional clarification pertaining to the incidence of cancer in the 2-county service area was provided in the 8/26/14 supplemental response and is illustrated in the graph below.

Service Area Cancer Rates Age Adjusted Rates per 100,000 Population



Source: Tennessee Cancer Registry Annual Reports; CN1408- 036, Item 7, 8/26/14 supplemental response

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- As indicated by the table, both counties had cancer rates per 100,000 population for the years 2005-2009 higher than the statewide rate of 477 per 100,000 population.
- Tennessee had a cancer incidence rate ranked 16th highest in the country. Its cancer mortality rate was ranked 6th highest.

The following items further highlight the need for the project:

- Enhance access of residents in service area to existing radiation therapy service and reduce outmigration to more distant providers.
- Continue commitment to modernization and enhancement of cancer diagnosis and treatment service capabilities.
- Develop array of cancer services focusing on diagnostic, treatment, and support services such as community education, pastoral care, patient support groups and nutrition services.
- Upgrade technology with new generation replacement equipment.
- Respond to needs of older population.
- Target high incidence of cancer in Macon and Sumner Counties as illustrated on the preceding page.

Primary Service Area

The service area of SRMC's existing radiation therapy service is Sumner and Macon Counties.

- Per the TDH summary report, the total population of the primary service area is estimated at 195,450 residents in calendar year CY 2014 increasing by approximately 6.2% to 207,527 residents in CY 2018.
- The total population of the state of Tennessee is expected to grow 2.8% from CY2014 to CY2018.
- The total 65+ age population is estimated at 28,811 residents in CY 2014 increasing approximately 12.9% to 32,539 residents in 2018 compared to a statewide change of 9.18% during this time period.
- The age 65 and older population accounts for approximately 15.9% of the total service area population compared to 15.8% statewide.
- The applicant estimates that approximately 15.4% of Sumner and Macon County residents are enrolled in TennCare compared to 18.8% statewide.

Historical and Projected Utilization

As indicated earlier, SRMC operates the only linear accelerator in Macon and Sumner Counties. The historical and projected utilization of SRMC's unit and its use by area residents and their use of other linear accelerator units in Davidson County are noted below. Table 1 provides the applicant's historical and projected utilization. Table 2 provides a snapshot of the use by residents of Sumner and Macon Counties of SRMC's unit and the units of providers in Davidson County.

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Table 3 provides a comparison of the service area's linear accelerator use rate (procedures per 1,000 population) to the Davidson County and statewide use rates from 2011 - 2013.

Table 1- SRMC's Historical and Projected Utilization

2011	2012	2013	% Change, '11-'13	Year 1	Year 2
4,038	4,043	3,979	-1.5%	4,375	4,450

Table 2 - Provider Utilization by Macon and Sumner County Residents

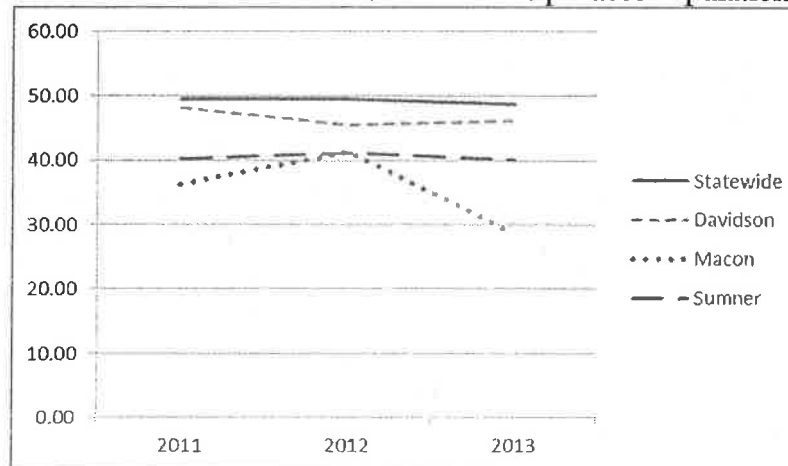
County	Treatments at SRMC - 2013	Treatments at Davidson County Hospitals	All other TN Hospitals	Total
Sumner	3,200	3,493	80	6,773
Macon	417	139	102	658
Total	3,617	3,632	182	7,431

Source: HSDA Equipment Registry, 2013 Service Utilization Records

Table 3.a - Linear Accelerator Treatments per 1000 Population

	2011	2012	2013
Davidson	47.95	45.39	46.07
Macon	36.10	41.29	28.66
Sumner	40.18	41.08	39.98
Statewide	49.52	49.46	48.66
	2011	2012	2013

Table 3.b - Linear Accelerator Treatments per 1000 Population



Based on the tables above, the following highlights are noted:

- Table 1 - SRMC's historical utilization appears to be trending slightly downward from 2011 to 2013. Projected utilization is expected to increase by approximately 10% from the 3 year historical average.

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- Table 2 - per HSDA Equipment Registry records, Macon and Sumner County residents accounted for approximately 91% of 3,979 total procedures performed by SRMC in 2013.
- Table 2 - as a comparison, Macon and Sumner County residents also accounted for 5.8% of 62,752 total procedures performed by Davidson County providers in 2013.
- Table 2 - per HSDA records, Skyline Medical Center's linear accelerator had the highest use by residents of the applicant's service area in 2013 (22.5% of 5,745 total procedures). The utilization of all other Davidson County providers by Sumner and Macon County residents was 5% or less per unit during the period.
- Table 2 - over 50% of service area residents' linear accelerator treatments took place at locations outside of Sumner County, primarily in Davidson County.
- Table 3 - the chart and trend line graph reflects that the Sumner and Macon County population use rates are significantly lower by comparison to the statewide and Davidson County use rates.
- Per the applicant, the lower use rates in Sumner and Macon Counties suggests the potential for higher volumes by SRMC's replacement unit (*Item 7, August 26, 2014 supplemental response*).
- Table 3 - the information helps support the applicant's case for recapturing some of the resident outmigration to other providers that could lead to a slight increase in utilization in the first year of the project from historical volumes (*10% from CY2013 volumes*).

Project Cost

Major costs are:

- \$4,449,022 for purchase of a replacement linear accelerator unit inclusive of 5-year maintenance, accessories (CT simulator and treatment planning system), sales tax, and freight (42.3% of the total project cost).
- \$3,798,000 for site preparation and build-out of radiation therapy suite in SRMC's existing outpatient facility (36% of the total project cost).
- Architect letter dated 3/7/14 attests to construction cost estimate and build-out in accordance with all applicable building and safety codes.
- Per HSDA records, the project's combined construction cost of \$330.50 per square foot (SF) is above the HSDA 3rd quartile combined construction cost of \$274.63/SF for hospital projects from 2011 -2013. Per the applicant, new construction of the 1,570 vault to house the unit, install shielding, etc., is the primary reason for the higher combined cost of the project.
- For other details on Project Cost, see the Project Cost Chart on page 16 of the original application.

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Historical Data Chart

- According to the revised Historical Data Chart, SRMC reported the following net income after capital expenditures; \$4,941,000 in 2011, \$4,304,000 in 2012, and \$6,406,00 for 2013
- In the course of HSDA staff review of the application, there appeared to be a difference of approximately \$4.4 million in Net Operating Income as reported in the Historical Data Chart and the Income Statement. Please see the clarification provided in Item 10 of the 8/26/14 supplemental response.

Projected Data Chart

The revised Projected Data Chart for the radiation therapy service reflects \$8,732,000 in total gross operating revenue on 4,375 procedures in Year 1 increasing by approximately 1.7% to \$8,881,000 on 4,450 procedures in Year Two. The Projected Data Chart reflects the following:

- Net operating income less capital expenditures for the applicant will equal \$516,000 in Year 1 decreasing to \$408,000 in Year 2 due in large part to start-up of annual maintenance service costs.
- Net operating revenue after bad debt, charity care, and contractual adjustments is expected average approximately 30% of gross revenue in the first two years of the project.
- Contractual adjustments accounts for the highest deductions from revenue averaging approximately 65% of gross revenue per year. It appears that the applicant's 35% Medicare/TennCare payor mix may help explain why contractual adjustments are higher for this service.
- Gross operating margin is approximately 6% of gross operating revenue and 4.6% in Year Two.

Charges

As clarified in Item 11 of the 8/26/14 supplemental response, the average charge per procedure information provided for Year 1 of the project is as follows:

- The proposed average gross charge per linear accelerator procedure is \$1,996; however the net charge is \$598.86 per procedure.
- Per the comparison provided on page 22 of the application, the Medicare allowable charges for the most common procedure classifications that apply to the service range from \$201.24 to \$1,781.12.
- According to the HSDA Equipment Registry, the applicant's \$1,996 gross charge is higher than both the 2013 linear accelerator 1st Quartile Charge of \$1,113.33 and the Median Charge of \$1,521.69.

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Medicare/TennCare Payor Mix

- The expected payor mix in Year 1 includes 28.5% for Medicare and 6.6% for TennCare.
- SRMC contracts with all TennCare MCOs in the service area: AmeriGroup, United Healthcare (AmeriChoice), and TennCare Select.
- Per Item 3, Supplemental 2, the applicant states that the Medicare payor mix may increase when adding Medicare Advantage.
- *Note to Agency Members: per The Rules of the TennCare Bureau, Chapter 1200-13-17-.01(15), the Medicare Part C program refers to the Medicare Advantage Program authorized under Part C of Title XVIII of the Social Security Act, through which beneficiaries may choose to enroll in private managed care plans that contract with the Centers for Medicare and Medicaid Services (CMS). These plans may be HMO, PPO or fee-for-service plans. They offer combined coverage of Part A, Part B, and, in most cases, Part D benefits. Some Medicare Advantage plans offer additional benefits not otherwise covered by Medicare.*

Financing

- A letter dated August 6, 2014 from Tom Butler Jr., CFO, Lifepoint Eastern Group, confirms that the parent company has the cash reserves to fund the estimated capital outlay required of the proposed project.
- Review of SRMC's Balance Sheet for the period ending December 13, 2013 revealed \$22,490,955 in total current assets, total current liabilities of \$7,983,125 and a current ratio of 2.82 to 1.0.
- *Note to Agency Members: current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.*

Staffing

- The service is under the clinical leadership of the hospital's cancer committee and the physician specialists on staff at SRMC involved in cancer care.
- A description of the committee's key activities and the composition of the medical staff was addressed in detail in Item 14 of the 8/24/14 supplemental response.
- The current and proposed staffing pattern of the service consists of 4.7 full time equivalent (FTE), including 2.7 FTE radiation therapy technicians, 1 FTE dosimetrist and 1 FTE Registered Nurse.

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Licensure/Accreditation

- SRMC is accredited by The Joint Commission and licensed by TDH. The applicant's cancer program is accredited by the American College of Surgeons Commission on Cancer Care.

The applicant has submitted the required information on corporate documentation, site control and a revised quote for the purchase of the linear accelerator inclusive of costs for maintenance/service and accessories that will be effective on the date of the Agency hearing of the application. Staff will have a copy of these documents available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency's office.

Should the Agency vote to approve this project, the CON would expire in three years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent, denied or outstanding Certificates of Need for this applicant.

Pending Applications

Sumner Regional Medical Center, CN1409-041, has a pending application that will be heard at the December 17, 2014 Agency meeting for the initiation of a PET service in an existing building located on the hospital's outpatient campus at Sumner Station, Gallatin, (Sumner County), TN. The estimated project cost is \$2,887,845.00.

LifePoint Hospitals, Inc. has a financial interest in this application and the following:

Outstanding Certificates of Need

Starr Regional Medical Center—Etowah, CN1404-009, has an outstanding Certificate of Need that will expire on September 1, 2017. The project was heard at the July 23, 2014 Agency meeting for the expansion of the hospital's existing ten (10) bed geri-psychiatric unit to fourteen (14) beds. The hospital will close four (4) general hospital beds at Etowah with the result that the licensed beds at Etowah (72) and the total consolidated licensed beds (190) for both the Etowah and Athens hospitals will not change. The estimated project cost is \$1,283,000. *Project Status Update: the project was recently approved.*

Southern Tennessee Medical Center, CN1402-005, has an outstanding Certificate of Need that will expire on July 1, 2017. The CON was approved at the May 28, 2014 Agency meeting for the initiation of mobile positron emission

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tomography (PET) services one half day per week at the main hospital campus. The estimated project cost is \$834,135.00. *Project Status: per e-mail from a representative of the hospital, the mobile PET service was initiated on or about June 22, 2014.*

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent, pending or denied applications, or outstanding Certificates of Need for other health care organizations proposing this type of service.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG
(10/8/14)

LETTER OF INTENT



State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in The Tennessean which is a newspaper
(Name of Newspaper)
of general circulation in Sumner, Tennessee, on or before August 10, 20 14,
(County) (Month / day) (Year)
for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Sumner Regional Medical Center an existing hospital
(Name of Applicant) (Facility Type-Existing)

with an ownership type of limited liability company intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: relocation of linear accelerator services to its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard, Gallatin, TN, and to initiate linear accelerator services at that location. An existing linear accelerator will be replaced as part of the project. The project will require build-out of approximately 9,150 sq. ft. of existing space and 1,570 sq. ft. of new construction. The total project cost is approximately \$10,512,421. The project does not involve a change in licensed bed capacity or the initiation of any service requiring a certificate of need, except the relocated linear accelerator service.

The anticipated date of filing the application is: August 15, 20 14

The contact person for this project is Dan Elrod Attorney
(Contact Name) (Title)

who may be reached at: Butler Snow LLP 150 3rd Avenue South, Suite 1600
(Company Name) (Address)

Nashville TN 37201 615 / 651-6702
(City) (State) (Zip Code) (Area Code / Phone Number)
[Signature] 8/8/2014 dan.elrod@butlersnow.com
(Signature) (Date) (E-mail Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

ORIGINAL APPLICATION

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BUTLER | SNOW

August 15, 2014

VIA HAND DELIVERY

Melanie M. Hill
Executive Director
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Sumner Regional Medical Center, Certificate of Need Application for Relocation
of Linear Accelerator Services

Dear Ms. Hill:

Enclosed is the original and two (2) copies of the certificate of need application referenced above, along with a check for the filing fee in the amount of \$23,600.

We respectfully request that the enclosed application be considered for placement on the Agency's consent calendar. Supporting this request we note the application by Sumner Regional Medical Center merely seeks authority to relocate its existing linear accelerator service to its existing outpatient campus at Sumner Station located about 6.9 miles from the main campus. No new service is being added to the service area and this relocation within the service area will not impact other providers.

Thank you for your attention to this request.

Very truly yours,

BUTLER SNOW LLP


Dan H. Elrod

clw
Enclosures

*The Pinnacle at Symphony Place
150 3rd Avenue South, Suite 1600
Nashville, TN 37201*

DAN H. ELROD
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22276643v1

BUTLER SNOW LLP

Sumner Regional Medical Center

Certificate of Need Application for Relocation of Linear Accelerator Services to Sumner Station

August 15, 2014

August 26, 2014

11:58am

1. Name of Facility, Agency, or InstitutionSumner Regional Medical Center (Sumner Station Campus)

Name

225 Big Station Camp Road

Street or Route

Sumner

County

Gallatin

City

TN

State

37066

Zip Code

2. Contact Person Available for Responses to QuestionsMichael Herman

Name

Chief Operating Officer

Title

Sumner Regional Medical Center

Company Name

Michael.Herman@LPNT.net

Email address

555 Hartsville Pike

Street or Route

Gallatin

City

TN

State

37066

Zip Code

COO

Association with Owner

615-328-6695

Phone Number

Fax Number

3. Owner of the Facility, Agency or InstitutionSumner Regional Medical Center, LLC

Name

615-72-8500

Phone Number

330 Seven Springs Way

Street or Route

Sumner

County

Brentwood

City

TN

State

37027

Zip Code

See Attachment A, Item 34. Type of Ownership of Control (Check One)A. Sole Proprietorship ☐B. Partnership ☐C. Limited Partnership ☐D. Corporation (For Profit) ☐E. Corporation (Not-for-Profit) ☐F. Government (State of TN or
Political Subdivision) ☐G. Joint Venture ☐H. Limited Liability Company ☒I. Other (Specify) ☐See Attachment A, Item 4

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5. **Name of Management/Operating Entity (If Applicable)**

N/A

Name

Street or Route

County

City

State

Zip Code

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. **Legal Interest in the Site of the Institution (Check One)**

A. Ownership

X

D. Option to Lease

B. Option to Purchase

E. Other (Specify)

C. Lease of Years

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

See Attachment A, Item 6

7. **Type of Institution (Check as appropriate--more than one response may apply)**A. Hospital (Specify) acute careX

H. Nursing Home

B. Ambulatory Surgical Treatment
Center (ASTC), Multi-Specialty

I. Outpatient Diagnostic Center

C. ASTC, Single Specialty

J. Rehabilitation Facility

D. Home Health Agency

K. Residential Hospice

E. Hospice

 L. Nonresidential
Substitution-Based Treatment
Center for Opiate Addiction

F. Mental Health Hospital

M. Birthing Center

G. Intellectual Disability
Institutional Habilitation Facility
(IDIHF) (ICF/IID formerly
(ICF/MR)

N. Other Outpatient Facility

O. Other (Specify)

8. **Purpose of Review (Check as appropriate--more than one response may apply)**

A. New Institution

G. Change in Bed Complement

B. Replacement/Existing Facility

[Please note the type of change
by underlining the appropriate
response: Increase, Decrease,
Designation, Distribution,
Conversion, Relocation]

C. Modification/Existing Facility

 D. Initiation of Health Care
Service as defined in TCA §
68-11-1607(4)
(Specify)

H. Change of Location

X

E. Discontinuance of OB Services

I. Other (Specify)

F. Acquisition of Equipment

9. **Bed Complement Data*****Please indicate current and proposed distribution and certification of facility beds.***

	<u>Current Beds Licensed</u>	<u>*CON</u>	<u>Staffed Beds</u>	<u>Beds Proposed</u>	<u>TOTAL Beds at Completion</u>
A. Medical	90	0	90	0	90
B. Surgical					
C. Long-Term Care Hospital					
D. Obstetrical	15	0	15	0	15
E. ICU/CCU	18	0	18	0	18
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric	12		12		12
J. Child/Adolescent Psychiatric					
K. Rehabilitation	20		20		20
L. Nursing Facility - SNF (Medicare only)					
M. Nursing Facility - NF (Medicaid only)					
N. Nursing Facility - SNF/NF (dually certified Medicaid/Medicare)					
O. Nursing Facility - Licensed (non-Certified)					
P. IDIHF					
Q. Adult Chemical Dependency					
R. Child and Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL	155	0	155	0	155

*CON-Beds approved but not yet in service

10. **Medicare Provider Number** 1447571658
Certification Type Acute Care Hospital

11. **Medicaid Provider Number** 044-0003
Certification Type Acute Care Hospital

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?**
 Yes
 No
 X NA

13. **Will this project involve the treatment of TennCare participants?** Yes

NOTE: **Section B** is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. **Section C** addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. **Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.**

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

- I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility, staffing, and how the project will contribute to the orderly development of adequate and effective healthcare.

Response:

Sumner Regional Medical Center ("SRMC") proposes to relocate its linear accelerator services from the main hospital to an existing outpatient campus, known as "Sumner Station," located on Big Station Camp Boulevard just off Vietnam Veterans Parkway, approximately 6.9 miles west of the main campus. This move will provide patients with a more convenient location for radiation therapy, as they will no longer have to come to the main hospital campus for services. As part of this project, Sumner Regional will replace its linear accelerator.

Sumner Regional is a 155 bed acute care hospital in Gallatin, TN. It is part of LifePoint Hospitals. LifePoint Hospitals is headquartered in Brentwood, TN. It operates 63 hospitals in 20 states, including 10 in Tennessee.

SRMC is one of 15 LifePoint hospitals that was recognized by the Joint Commission in 2013 as a Top Performer in Key Quality Measures. The Sumner Station campus of SRMC currently includes outpatient imaging and outpatient rehabilitation services. SRMC's primary service area for radiation therapy is Sumner and Macon Counties.

The need for the project is provide outpatient radiation therapy patients with easier access to the service and to alleviate the burden on patients from traffic, congestion and wayfinding issues at the main campus. As part of the project, the existing linear accelerator, which has been in service since 1996, will be replaced. The linear accelerator is replacement equipment, and thus not considered as major medical equipment. The cost of the linear accelerator has been included as part of the project cost, in order to capture the full scope of the project.

The project will require renovation and build-out of approximately 9,150 sq. ft. of shelled space in an existing building and approximately 1,570 sq. ft. of new construction for the linear accelerator vault. The total project cost, including the replacement linear accelerator,

is approximately \$10,512,770, which will be funded by a capital contribution from the applicant's parent, LifePoint Hospitals. No new staff will be required for the relocated radiation therapy service.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. For the establishment or modification of a healthcare institution describe the development of and need for the proposal. Health care institutions include:

1. Nursing home
2. Hospital
3. Ambulatory Surgical Treatment Center
4. Birthing Center
5. Mental Health Hospital
6. Intellectual Disability Institutional Habilitation Facility
7. Home Care Organization (Home Health Agency or Hospice Agency)
8. Outpatient Diagnostic Center
9. Rehabilitation Facility
10. Residential Hospice
11. Nonresidential Substitution-based Treatment Center for Opiate Addiction

Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applications with construction, modification and/or renovation costs should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

Response: The project includes approximately 10,720 square feet, which includes 9,150 square feet of build-out construction for the radiation oncology suite and 1,570 square feet of new construction for the linear accelerator vault. The project will also site improvements, including additional parking and a covered entrance for the radiation oncology suite. The build-out will include the patient waiting area, business office, exam rooms, CT/simulator room, doctors' offices, and other support spaces.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change

in bed allocations and describe the impact the bed change will have on the existing services.

C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

1. Adult Psychiatric Services
2. Hospital-Based Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Burn Units
4. Cardiac Catheterization Services
5. Child and Adolescent Psychiatric Services
6. Extracorporeal Lithotripsy
7. Home Health Services
8. Hospice Services
9. Magnetic Resonance Imaging (MRI)
10. Neonatal Intensive Care Unit
11. Opiate Addiction Treatment provided through a Non-Residential Substitution-Based Treatment Center for Opiate Addiction
12. Open Heart Surgery
13. Positron Emission Tomography
14. Radiation Therapy/Linear Accelerator
15. Rehabilitation Services
16. Swing Beds
17. Discontinuation of any obstetrical or maternity service
18. Closure of a Critical Access Hospital
19. Elimination in a critical access hospital of any service for which a certificate of need is required

Response: Not applicable.

D. Describe the need to change location or replace an existing facility.

Response: SRMC has a need to change the location of its existing radiation therapy service order to enhance patient access, and to alleviate the difficulties that patients currently encounter in with traffic, parking and wayfinding when receiving treatments at the main campus. The outpatient campus at Sumner Station is the ideal solution, because it makes use of an existing building conveniently located off a main highway (Vietnam Veterans Parkway) with easy access, improved parking, and a canopied entrance. This project will also facilitate the needed replacement of SRMC's linear accelerator with a new state-of-the-art unit that assures the continuation of modern radiation therapy services in the community.

E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. For major medical equipment (not replacing existing equipment):

a. Describe the new equipment, including:

1. Brief description of equipment including characteristics such as fixed or mobile; expected vendor and model (if known); for MRI use descriptors such as Tesla strength, open/closed bore; for linear accelerators use descriptors such as MeV strength, IMRT/IGRT/SRS capability; etc.;
2. Total cost (As defined by Agency Rule 0720-9-.01(13))

- a. By Purchase or
- b. By Lease;
- 3. Expected useful life;
- 4. List of clinical applications to be provided;
- 5. Documentation of FDA approval; and
- 6. For mobile major medical equipment list all sites that the unit is currently serving and its current schedule of operations at those sites.

Response: The replacement linear accelerator proposed as part of this project is technically not major medical equipment because it replaces an existing unit, but in the interest of full project description, the new linear accelerator will be a Varian TrueBeam unit with CT simulator. The unit will be capable of providing conventional radiation therapy services, as well as IMRT, IGRT and SRS. The total cost of the unit with all accessories and service contract for 5 years is \$3,729,787. A copy of the FDA approval is at Attachment B. II, E., 1.

- b. Provide current and proposed schedules of operations.

Response: The hours and days of operation of the existing radiation therapy service are 7:30 – 4:30 Monday through Friday and the days and hours will not change at the new location.

- 2. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment.

Response: The linear accelerator will be purchased. The vendor quote is attached under Attachment B.II, E., 2.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

- 1. Size of site (*in acres*);
- 2. Location of structure on the site; and
- 3. Location of the proposed construction.
- 4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

Response: Plot plan attached under Attachment B.III.(A).

- (B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients. ***(Not applicable to home health or hospice agency applications.)***

Response: Sumner Station is located on Big Station Camp Boulevard, in between Long Hollow Pike and Vietnam Veterans Bypass. There is not direct bus service to the facility, but Sumner Station is easily accessible by car. Additionally, Mid-Cumberland Human Resources Agency RTS Public Transit serves the area.

- IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper. **(Not applicable to home health or hospice agency applications.)**

NOTE: **DO NOT SUBMIT BLUEPRINTS**. Simple line drawings should be submitted and need not be drawn to scale.

Response: The floor plan is attached as Attachment B, IV.

- V. For a Home Health Agency or Hospice, identify:

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth, if applicable.
 - a. Please discuss how the proposed project will relate to the 5 Principles for Achieving Better Health found in the State Health Plan. Please list each principle and follow it with a response.

Response:Health Lives

This project will promote the healing of cancer patients in the community by making state-of-the-art radiation therapy available at a convenient location that will be more accessible than the existing service. The project will also reduce the stress on sick patients by making it easier to access care.

Access to Care

The outpatient radiation therapy center will be available to all patients. SRMC is contracted with all existing TennCare MCOs in the area, and SRMC intends to continue its participation in all TennCare MCOs when the new MCO contracts are implemented in 2015.

Economic Efficiencies

This project achieves economic efficiency because it makes use of an existing building on an existing outpatient campus in order to provide the benefits of enhanced convenience and accessibility for cancer patients. The project will not result in any increase in patient charges or require additional staffing.

Quality of Care

The project contributes to quality of care by replacing a linear accelerator that is at the end of its useful life with a state-of-the-art unit that assures the stability and availability of high quality radiation therapy treatment for many years to come. SMRC's commitment to quality care is evidenced by its designation by the Joint Commission as a Top Performer in Key Quality Measures.

Health Care Workforce

This project will not require any additional staffing and thus will not have an effect on the health care workforce.

- b. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9 of the Guidelines for Growth) here.

Response: *This involves the relocation of an existing hospital services, so the criteria related to the **CONSTRUCTION, RENOVATION, EXPANSION, AND REPLACEMENT OF HEALTH CARE INSTITUTIONS** would appear to be applicable:*

- a. *The applicant should provide plans which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.*

SRMC did not develop any plans for onsite renovation, because the major goal of the project is to get radiation therapy to a location that is away from the main campus and more convenient for patients. SRMC also did not consider alternate sites, because the Sumner Station location has the

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obvious advantages of using a building that already exists and is owned by SRMC.

- b. The applicant should demonstrate that there is an acceptable existing or projected future demand for the proposed project.

The existing radiation service at SRMC is well-utilized. Below is a table with total number of treatments for the past 3 years, 2014 annualized and for the first 2 years following completion of the project. While the treatment volumes are below the minimum guideline in the State Health Plan of 6,000 per year, the volumes are sufficient for financial viability and the elimination of the service in Sumner County would seriously compromise the availability of radiation therapy for the residents of Sumner and Macon counties.

2011 – 4,038

2012 - 4,043

2013 – 3,979

2014 - 4,252 (annualized based on first 6 months)

Year 1 - 4,375

Year 2 - 4,450

- c. Applications that include a Change of Site for a proposed new health care institution (one having an outstanding and unimplemented CON), provide a response to General Criterion and Standards (4)(a-c) of the Guidelines for Growth.

Response: Not applicable.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

Response: SRMC's long-range plan includes the intention to maintain and upgrade services and technology to meet community expectations for modern up-to-date care. This project is consistent with this plan because it will replace an 18 year old linear accelerator with a level of linear accelerator technology that is the same as exists in Nashville and other medical center locations in the state.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. **Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).**

Response: SRMC's primary service area for radiation therapy is Sumner and Macon Counties. From 2010-2012, approximately 84% of SRMC's radiation therapy patients came from these two counties. A map showing the service area is attached as Attachment C., Need - 3.

4. A. 1) Describe the demographics of the population to be served by this proposal.

Response: See demographic information at Attachment C. Need - 4.A.(1).

- 2) Using population data from the Department of Health, enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau, please complete the following table and include data for each county in your proposed service area:

Demographic Variable/ Geographic Area	Sumner County	Macon County	Service Area Total	State of TN Total
Total Population – Current Year 2014	172,282	23,188	195,470	6,588,698
Total Population – Projected Year 2017	180,639	23,894	204,533	6,772,022
Total Population - % change	4.85%	3%	4.6%	2.78%
*Target Population – Current Year	25,164	3,647	28,811	981,984
*Target Population – Projected Year	28,527	4,012	32,539	1,072,143
Target Population - % Change	13.36%	10%	12.9%	9.18%
Target Population – Projected Year as % of Total	15.8%	16.8%	15.9%	15.8%
Median Age	38.7	38.3		38
Median Household Income	\$55,560	\$35,452		\$44,140
TennCare Enrollees	24,135	6,061	30,196	1,241,028
TennCare Enrollees as % of Total	14%	26%	15.4%	18.8%
Persons Below Poverty Level	16,260	5,295	21,555	1,129,610
Persons Below Poverty Level as % of Total	9.8%	23.5%	11.4%	17.3%

**Target Population is 65+ per application instructions. Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics; TennCare Bureau; U.S. Census Bureau.*

- B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Response: A significant portion (28.4%) of SRMC's radiation therapy patients is covered by Medicare. Elderly cancer patients receiving multiple radiation therapy treatments will particularly benefit from the project, because this category of patients is most likely to experience difficulty with traffic and congestion when traveling to the main campus for treatments. In addition, SRMC is contracted with all TennCare MCOs and the new facility will thus be available to all TennCare patients.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g., cases,

procedures, visits, admissions, etc. Projects including surgery should report the number of cases and the average number of procedures per case.

Response: There are no approved but unimplemented CONs in the service area. SRMC is the only provider of radiation therapy in the service area.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization through the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

Response:

	2011	2012	2013	Year 1	Year 2
SRMC	4,038	4,043	3,979	4,375	4,450

2011-2013 from HSDA Equipment Registry

The Applicant projects slight growth in volumes based on increased population and reduced outmigration due to improved technology.

ECONOMIC FEASIBILITY

- Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
 - All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
 - The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
 - The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
 - For projects that include new construction, modification, and/or renovation; documentation must be provided from a licensed architect or construction professional that support the estimated construction costs. Please provide a letter that includes:
 - a general description of the project;

- 2) estimate of the cost to construct the project to provide a physical environment, according to applicable federal, state and local construction codes, standards, specifications, and requirements; and
- 3) attesting that the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements including the most recent AIA Guidelines for Design and Construction of Hospital and Health Care Facilities.

Response: Architect letter attached at Attachment C., Economic Feasibility - 1.

PROJECT COSTS CHART

A. Construction and equipment acquired by purchase:		
1.	Architectural and Engineering Fees	<u>\$450,000</u>
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	<u>\$25,000</u>
3.	Acquisition of Site	<u></u>
4.	Preparation of Site	<u>\$255,000</u>
5.	Construction Costs	<u>\$3,543,000</u>
6.	Contingency Fund	<u>\$510,000</u>
7.	Fixed Equipment (Not included in Construction Contract)	<u>\$4,449,022</u>
8.	Moveable Equipment (List all equipment over \$50,000)	<u>\$1,256,799</u> <u>(no items over \$50,000)</u>
9.	Other (Specify) _____	<u></u>
B. Acquisition by gift, donation, or lease:		
1.	Facility (inclusive of building and land)	<u></u>
2.	Building only	<u></u>
3.	Land only	<u></u>
4.	Equipment (Specify) _____	<u></u>
5.	Other (Specify) _____	<u></u>
C. Financing Costs and Fees:		
1.	Interim Financing	<u></u>
2.	Underwriting Costs	<u></u>
3.	Reserve for One Year's Debt Service	<u></u>
4.	Other (Specify) _____	<u></u>
D.	Estimated Project Cost (A+B+C)	<u>\$10,488,821</u>
E.	CON Filing Fee	<u>\$23,600</u>
F.	Total Estimated Project Cost (D+E)	<u></u>
TOTAL		<u>\$10,512,421</u>

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (**Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.**)

- ☐ A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
- ☐ D. Grants--Notification of intent form for grant application or notice of grant award; or
- ☒ E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- ☐ F. Other—Identify and document funding from all other sources.

Response: Funding confirmation attached at Attachment C, Economic Feasibility -2.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

Response: According to the HSDA's website, the 2011-2013 construction costs for hospitals in the 3rd quartile were \$249.00 per sq. ft. for renovation, \$324 per sq. ft. for new construction and \$274.63 per sq. ft. combined. The construction costs for the project are projected to be \$260 per sq. ft. for renovation, \$741.60 per sq. ft. for new construction and \$330.50 per sq. ft. combined. In connection with the cost of new construction, it should be noted that the only new construction is the vault for the linear accelerator, which is very expensive construction due to the required shielding.

4. Complete Historical and Projected Data Charts on the following two pages--**Do not modify the Charts provided or submit Chart substitutions!** Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the **Proposal Only** (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should also include any management fees paid by agreement to third party entities not having common ownership with the applicant. Management fees should not include expense allocations for support services, e.g., finance, human resources, information technology,

legal, managed care, planning marketing, quality assurance, etc. that have been consolidated/centralized for the subsidiaries of a parent company.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Response: Average gross charge per treatment is \$1,996, average deduction is \$1,397 and average net charge is \$599.

36 HISTORICAL DATA CHART

SUPPLEMENTAL- # 1

August 26, 2014

11:58am

Give information for the last *three* (3) years for which complete data are available for the facility or agency. The fiscal year begins in January (Month).

	Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
A. Utilization Data (Adjusted Admissions)	<u>14,330</u>	<u>15,146</u>	<u>15,967</u>
B. Revenue from Services to Patients			
1. Inpatient Services	<u>\$147,022,000</u>	<u>\$178,940,000</u>	<u>\$222,998,000</u>
2. Outpatient Services	<u>162,648,000</u>	<u>196,626,000</u>	<u>221,909,000</u>
3. Emergency Services	<u>34,577,000</u>	<u>41,567,000</u>	<u>52,971,000</u>
4. Other Operating Revenue (Specify) _____	<u>2,312,000</u>	<u>2,145,000</u>	<u>1,055,000</u>
Gross Operating Revenue	<u>\$346,559,000</u>	<u>\$419,278,000</u>	<u>\$498,923,000</u>
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	<u>\$221,391,000</u>	<u>\$286,650,000</u>	<u>\$351,127,000</u>
2. Provision for Charity Care	<u>8,248,000</u>	<u>8,372,000</u>	<u>9,247,000</u>
3. Provisions for Bad Debt	<u>14,402,000</u>	<u>18,846,000</u>	<u>24,538,000</u>
Total Deductions	<u>\$244,041,000</u>	<u>\$313,868,000</u>	<u>\$384,912,000</u>
NET OPERATING REVENUE	<u>\$102,518,000</u>	<u>\$105,410,000</u>	<u>\$114,011,000</u>
D. Operating Expenses			
1. Salaries and Wages	<u>\$ 45,972,000</u>	<u>\$ 45,996,000</u>	<u>\$ 48,697,000</u>
2. Physician's Salaries and Wages	<u> </u>	<u> </u>	<u> </u>
3. Supplies	<u>16,054,000</u>	<u>16,662,000</u>	<u>17,116,000</u>
4. Taxes	<u>6,945,000</u>	<u>6,959,000</u>	<u>10,112,000</u>
5. Depreciation	<u>9,397,000</u>	<u>9,640,000</u>	<u>8,408,000</u>
6. Rent	<u>507,000</u>	<u>171,000</u>	<u>618,000</u>
7. Interest, other than Capital	<u> </u>	<u> </u>	<u> </u>
8. Management Fees:			
a. Fees to Affiliates	<u>3,741,000</u>	<u>4,090,000</u>	<u>4,408,000</u>
b. Fees to Non-Affiliates	<u> </u>	<u> </u>	<u> </u>
9. Other Expenses – Specify on Page 21	<u>14,961,000</u>	<u>17,589,000</u>	<u>18,246,000</u>
Total Operating Expenses	<u>\$ 97,577,000</u>	<u>\$101,106,000</u>	<u>\$107,605,000</u>
E. Other Revenue (Expenses) – Net (Specify) _____	<u>\$ _____</u>	<u>\$ _____</u>	<u>\$ _____</u>
NET OPERATING INCOME (LOSS)	<u>\$ 4,941,000</u>	<u>\$ 4,304,000</u>	<u>\$ 6,406,000</u>
F. Capital Expenditures			
1. Retirement of Principal	<u>\$ _____</u>	<u>\$ _____</u>	<u>\$ _____</u>
2. Interest	<u> </u>	<u> </u>	<u> </u>
Total Capital Expenditures	<u>\$ _____</u>	<u>\$ _____</u>	<u>\$ _____</u>
NET OPERATING INCOME (LOSS)			
LESS CAPITAL EXPENDITURES	<u>\$ 4,941,000</u>	<u>\$ 4,304,000</u>	<u>\$ 6,406,000</u>

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year <u>2017</u>	Year <u>2018</u>
A. Utilization Data (R.T. Treatments)	<u>4,375</u>	<u>4,450</u>
B. Revenue from Services to Patients		
1. Inpatient Services	\$ <u>137,000</u>	\$ <u>137,000</u>
2. Outpatient Services	<u>8,595,000</u>	<u>8,744,000</u>
3. Emergency Services	<u> </u>	<u> </u>
4. Other Operating Revenue (Specify) <u> </u>	<u> </u>	<u> </u>
Gross Operating Revenue	\$ <u>8,732,000</u>	\$ <u>8,881,000</u>
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	\$ <u>5,676,000</u>	\$ <u>5,773,000</u>
2. Provision for Charity Care	<u>175,000</u>	<u>178,000</u>
3. Provisions for Bad Debt	<u>262,000</u>	<u>266,000</u>
Total Deductions	\$ <u>6,112,000</u>	\$ <u>6,217,000</u>
NET OPERATING REVENUE	\$ <u>2,620,000</u>	\$ <u>2,664,000</u>
D. Operating Expenses		
1. Salaries and Wages	\$ <u>600,000</u>	\$ <u>604,000</u>
2. Physician's Salaries and Wages	<u> </u>	<u> </u>
3. Supplies	<u>39,000</u>	<u>43,000</u>
4. Taxes	<u>330,000</u>	<u>261,000</u>
5. Depreciation	<u>973,000</u>	<u>973,000</u>
6. Rent	<u> </u>	<u> </u>
7. Interest, other than Capital	<u> </u>	<u> </u>
8. Management Fees	<u> </u>	<u> </u>
a. Fees to Affiliates	<u> </u>	<u> </u>
b. Fees to Non-Affiliates	<u> </u>	<u> </u>
9. Other Expenses – Specify on Page 21	<u>162,000</u>	<u>375,000</u>
Total Operating Expenses	\$ <u>2,104,000</u>	\$ <u>2,256,000</u>
E. Other Revenue (Expenses) – Net (Specify) <u> </u>	\$ <u> </u>	\$ <u> </u>
NET OPERATING INCOME (LOSS)	\$ <u>516,000</u>	\$ <u>408,000</u>
F. Capital Expenditures		
1. Retirement of Principal	\$ <u> </u>	\$ <u> </u>
2. Interest	<u> </u>	<u> </u>
Total Capital Expenditures	\$ <u> </u>	\$ <u> </u>
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$ <u>516,000</u>	\$ <u>408,000</u>

HISTORAL DATA CHART – OTHER EXPENSES

August 26, 2014
11:58amOTHER EXPENSES CATEGORIES

	Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
1. Professional Fees	\$ <u>2,564,000</u>	\$ <u>2,597,000</u>	\$ <u>3,472,000</u>
2. Contract Services	<u>4,833,000</u>	<u>5,323,000</u>	<u>5,291,000</u>
3. Repairs and Maintenance	<u>3,485,000</u>	<u>3,485,000</u>	<u>3,854,000</u>
4. Utilities	<u>2,583,000</u>	<u>2,584,000</u>	<u>2,665,000</u>
5. Insurance	<u>(181,000)</u>	<u>843,000</u>	<u>604,000</u>
6. Investment Income	<u>(89,000)</u>		
7. Other (Marketing, Recruiting, etc.)	<u>1,766,000</u>	<u>2,757,000</u>	<u>2,360,000</u>
Total Other Expenses	\$ <u>14,961,000</u>	\$ <u>17,589,000</u>	\$ <u>18,246,000</u>

PROJECTED DATA CHART – OTHER EXPENSES

OTHER EXPENSES CATEGORIES

	Year <u>2017</u>	Year <u>2018</u>
1. Professional Fees	\$ <u>85,000</u>	\$ <u>85,000</u>
2. Contract Services	<u>77,000</u>	<u>77,000</u>
3. Repairs and Maintenance		<u>213,000</u>
4.		
5.		
6.		
7.		
Total Other Expenses	\$ <u>162,000</u>	\$ <u>375,000</u>

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Response: See charge information in B. below. The project will not have any impact on patient charges.

- B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response: Recently approved projects are (1) East Tennessee Radiation Therapy Treatment Services, CN1108-030A, which projected average charges per treatment of \$1,251 and (2) Maury Regional Medical Center, CN1307-026, which projected average charges per treatment of \$995. SRMC's per treatment charge for 2017 is projected to be \$1,996. A comparison of SRMC's charges for commonly encountered radiation therapy CPT codes with the Medicare allowable is as follows:

<u>CPT Code</u>	<u>SRMC Gross Charge</u>	<u>Medicare Allowable</u>
77301	\$4,228.36	\$1,781.12
77418	\$1,945.21	\$354.69
77295	\$4,228.36	\$447.89
77413	\$719.80	\$201.24
77414	\$719.80	\$226.66

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness; how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Response: The project will not result in an increase in charges. As indicated in the Projected Data Chart, the project will achieve positive financial results in the first year.

8. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Response: SRMC is contracted with all TennCare plans that operate in Middle Tennessee and it is committed to do so in the future. SRMC's projected gross revenues for radiation therapy from TennCare/Medicaid in year 1 are projected to be \$578,932 and gross revenues from Medicare are projected to be \$2,480,761.

9. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying

notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-9.

Response: SRMC does have an audited financial statement, but it's 2013 unaudited balance sheet and income statement are attached under Attachment C, Economic Feasibility - 9.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Response: Given that SRMC already owns the building at Sumner Station, and light of the outpatient services and medical offices that are on site at Sumner Station, SRMC did not consider alternative sites. Any other site would have been substantially more expensive because of the need to purchase land and construct a building or the need to lease space.

- b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

Response: One of the principal goals of this project is to make radiation therapy service more convenient and accessible. This goal necessarily excludes leaving the service on SRMC's main campus. The best option for relocation is Sumner Station for the reasons stated above.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

Response: A list of managed care contracts is attached under Attachment C, Contribution to the Orderly Development of Health Care - 1.

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

Response: This project will have only positive effects, because of improved patient convenience. In addition, SRMC believes the updated linear accelerator will enhance the confidence of Sumner and Macon county residents that they can receive first-class treatment in their community rather than making multiple trips to Nashville. SRMC is the only provider of

radiation therapy in the service area, so the project will not affect any other provider in the service area.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Response: *The current and proposed staffing pattern for the radiation therapy service, along with salaries, are as follows:*

<u><i>Position</i></u>	<u><i>FTE</i></u>	<u><i>Salary</i></u>
<i>Dosimetrist</i>	<i>1</i>	<i>\$121,825</i>
<i>Radiation Therapy Technologists</i>	<i>2.7</i>	<i>\$51,611 - \$76,327</i>
<i>R.N.</i>	<i>1.0</i>	<i>\$69,825</i>

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities licensing requirements.

Response: *SRMC currently has the staff to operate the new facility.*

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

Response: *SRMC has reviewed and understands licensing and certification requirements applicable to its medical and clinical staff.*

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

Response: *Pertinent to this application, SRMC has an agreement with Austin Peay University, under which SRMC is a clinical training site for radiation therapy technologists. The Sumner Station campus is covered by this agreement.*

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Substance Abuse Services, the Department of Intellectual and Developmental Disabilities, and/or any applicable Medicare requirements.

Response: *SRMC has viewed and understands the licensing requirements of the Department of Health.*

- (b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure: *Tennessee Department of Health*

Accreditation: *Joint Commission. SRMC's cancer program is accredited by the American College of Surgeons Commission on Cancer Care.*

- (c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Response: *SRMC is accredited by the Joint Commission and its cancer program is accredited by the American College of Surgeons Commission on Cancer Care. A copy of SRMC's license from the Tennessee Department of Health is attached under Attachment C, Contribution to the Orderly Development of Health Care – 7(c).*

- (d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction. Please also discuss what measures the applicant has or will put in place to avoid being cited for similar deficiencies in the future.

Response: *A copy of SRMCs' most recent survey and the plan of correction relative to the survey is attached under Attachment C., Orderly Development of Health Care -7(d).*

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Response: *There are no judgments or orders to be reported in response to this item.*

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project

Response: *There are no judgments to be reported in response to this item.*

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Response: *SRMC will provide to the Health Services and Development Agency the information described in this item.*

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

Response: Proof of Publication Attached.

NOTIFICATION REQUIREMENTS

(Applies only to Nonresidential Substitution-Based Treatment Centers for Opiate Addiction)

Please note that Tennessee Code Annotated 68-11-1607(c)(3) states that "...Within ten (10) days of filing an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located, the member of the House of Representatives and the Senator of the General Assembly representing the district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential substitution based treatment center for opiate addiction has been filed with the agency by the applicant."

Please provide this documentation.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

CLASSIFIED ads

Public Notices**Public Notices**

0101757852

**NOTIFICATION OF INTENT TO APPLY FOR A
CERTIFICATE OF NEED**

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that:

Sumner Regional Medical Center, an existing hospital with an ownership type of limited liability company intends to file an application for a Certificate of Need for relocation of linear accelerator services to its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard, Gallatin, TN, and to initiate linear accelerator services at that location. An existing linear accelerator will be replaced as part of the project. The project will require build-out of approximately 9,150 sq. ft. of existing space and 1,570 sq. ft. of new construction. The total project cost is approximately \$10,512,421. The project does not involve a change in licensed bed capacity or the initiation of any service requiring a certificate of need, except the relocated linear accelerator service.

The anticipated date of filing the application is: August 15, 20 14

The contact person for this project is Dan Elrod, Attorney, who may be reached at: Butler Snow LLP, 150 3rd Avenue South, Suite 1600, Nashville, TN 37201 615 / 651-6702

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development
Agency

Andrew Jackson Building, 9th floor
502 Deaderick Street
Nashville, Tennessee 37243

(A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and
(B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
2. If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph*, please state below any request for an extended schedule and document the "good cause" for such an extension.

Form HF0004
Revised 08/01/2012
Previous Forms are obsolete

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. §68-11-1609(c): Nov. 2014

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

Phase	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed	30	Dec. 2014
2. Construction documents approved by the Tennessee Department of Health	210	Jun. 2015
3. Construction contract signed	210	Jun. 2015
4. Building permit secured	240	Aug. 2015
5. Site preparation completed	N/A	N/A
6. Building construction commenced	270	Sept. 2015
7. Construction 40% complete	425	Jan. 2016
8. Construction 80% complete	550	May 2016
9. Construction 100% complete (approved for occupancy)	650	Aug. 2016
10. *Issuance of license	680	Sept. 2016
11. *Initiation of service	680	Sept. 2016
12. Final Architectural Certification of Payment	710	Oct. 2016
13. Final Project Report Form (HF0055)	710	Oct. 2016

* For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

AFFIDAVIT

STATE OF Tennessee
 COUNTY OF Davidson

Don H Elrod, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

[Signature]

SIGNATURE/TITLE

Sworn to and subscribed before me this 15th day of August, 2014 a Notary
 (Month) (Year)

Public in and for the County/State of Davidson County, Tennessee

Sharron C. Couch

NOTARY PUBLIC

My commission expires 3 8 2016
 (Month/Day) (Year)



My Commission Expires MAR. 8, 2016

Attachment A, Item 4

Organizational Chart

Delaware

PAGE 1

The First State


I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF FORMATION OF "SUMNER REGIONAL MEDICAL CENTER, LLC", FILED IN THIS OFFICE ON THE NINETEENTH DAY OF MAY, A.D. 2010, AT 4:11 O'CLOCK P.M.



4825590 8100

100536424

You may verify this certificate online
at corp.delaware.gov/authver.shtml


Jeffrey W. Bullock, Secretary of State
AUTHENTICATION: 8005193

DATE: 05-20-10



STATE OF TENNESSEE
Tre Hargett, Secretary of State
 Division of Business Services
 William R. Snodgrass Tower
 312 Rosa L. Parks AVE, 6th FL
 Nashville, TN 37243-1102

BUTLER SNOW LLP
 ATTN: DAN H. ELROD
 STE 1600
 150 3RD AVE S
 NASHVILLE, TN 37201-2046

August 13, 2014

Request Type: Certificate of Existence/Authorization

Request #: 0136177

Issuance Date: 08/13/2014

Copies Requested: 1

Document Receipt

Receipt #: 1610055

Filing Fee: \$20.00

Payment-Check/MO - BUTLER SNOW LLP, RIDGELAND, MS

\$20.00

Regarding: Sumner Regional Medical Center, LLC

Filing Type: Limited Liability Company - Foreign

Formation/Qualification Date: 05/25/2010

Status: Active

Duration Term: Perpetual

Control #: 632152

Date Formed: 05/19/2010

Formation Locale: DELAWARE

Inactive Date:

CERTIFICATE OF AUTHORIZATION

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

Sumner Regional Medical Center, LLC

* is a Limited Liability Company formed in the jurisdiction set forth above and is authorized to transact business in this State;

* has paid all fees, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

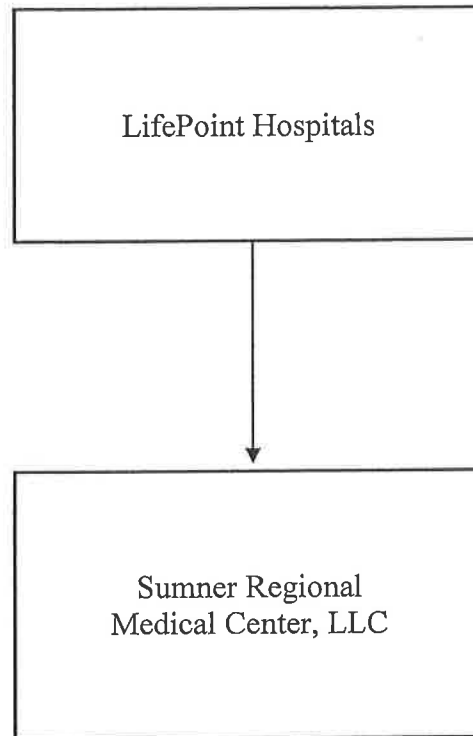
* has appointed a registered agent and registered office in this State;

* has not filed an Application for Certificate of Withdrawal.

Tre Hargett
 Secretary of State

Processed By: Nichole Hambrick

Verification #: 008304628



Note: This chart shows only the entities pertinent to the application. It is not possible to produce a chart that includes all 58 hospitals operated by LifePoint.

Attachment B, II, E, 1

FDA Approval



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Ms. Vy Tran
Vice President, Regulatory Affairs and Quality Assurance
Varian Medical Systems, Inc.
3100 Hansen Way, m/s C-255
PALO ALTO, CA 94304-1038

Re: K123291

Trade/Device Name: TrueBeam Radiotherapy Treatment System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 19, 2012
Received: October 22, 2012

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Ms. Vy Tran

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

~~If you desire specific advice for your device or our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of In Vitro Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to~~
<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

TrueBeam Radiotherapy Treatment System**Indications for Use**510(k) Number (if known): K123291Device Name: TrueBeam Radiotherapy Treatment System**Indications for Use:**

TrueBeam is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

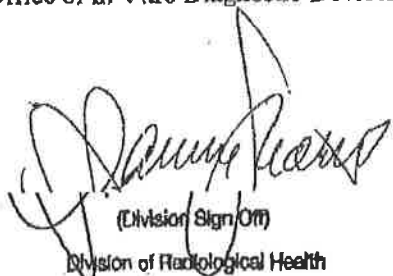
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K123291 |Page 1 of 1

Date: October 2012

Attachment B, III(A)

Plot Plan

SITE IMPROVEMENT AREA
PROJECT LOCATION

24.57 ACRES

BIG STATION CAMP ROAD

VIETNAM VETERANS PARKWAY
STATE ROUTE 386

RADIATION ONCOLOGY UNIT at SUMNER STATION for SUMNER REGIONAL MEDICAL CENTER

GALLATIN, TN 37066

03/07/2014 - C.O.N. SUBMITTAL - NOT FOR CONSTRUCTION

HINSON MILLER KICKIRILLO ARCHITECTS PLLC

SITE IMPROVEMENT=37,000 SF

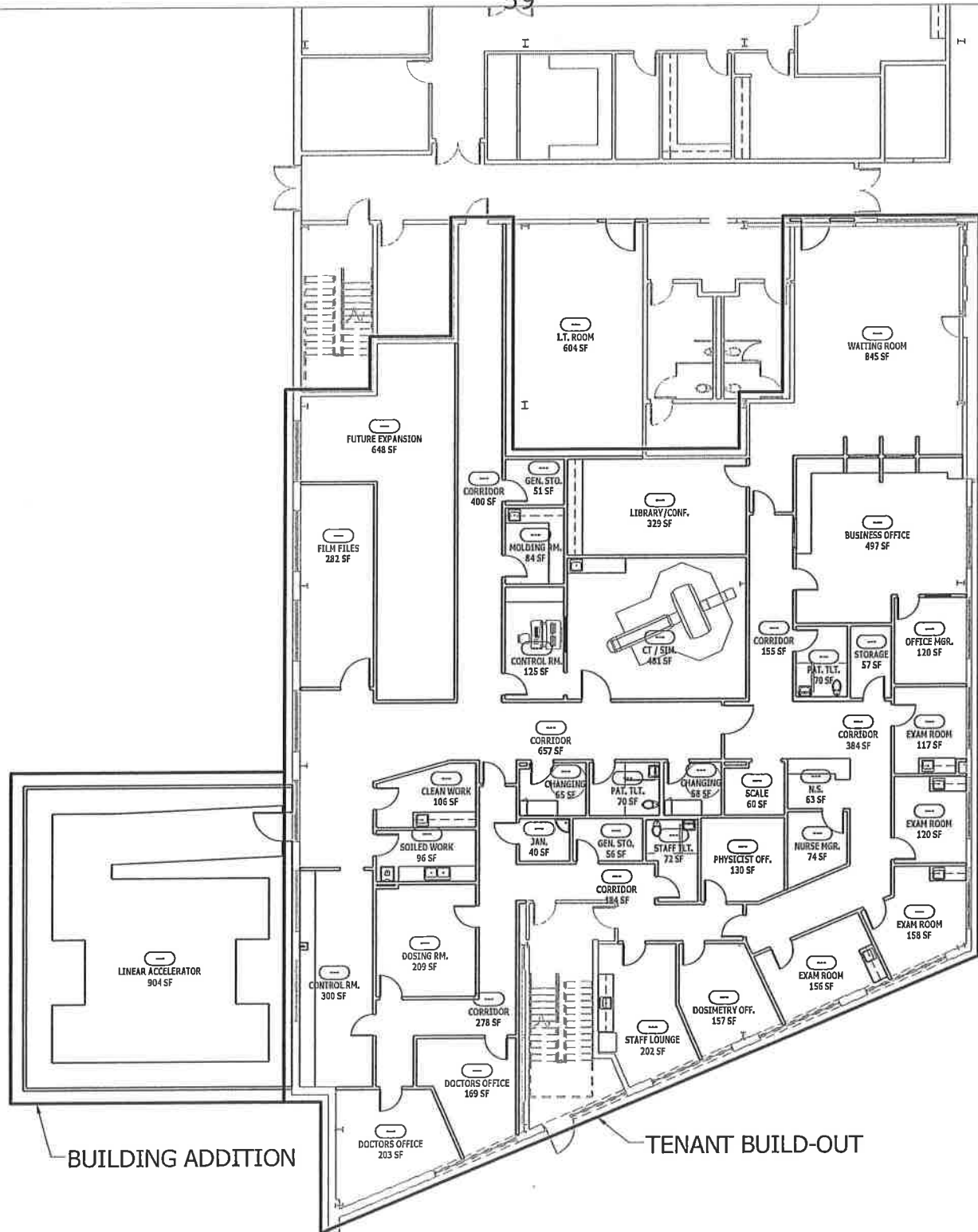


57

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Attachment B, IV

Floor Plan



RADIATION ONCOLOGY UNIT at SUMNER STATION for SUMNER REGIONAL MEDICAL CENTER

GALLATIN, TN 37066

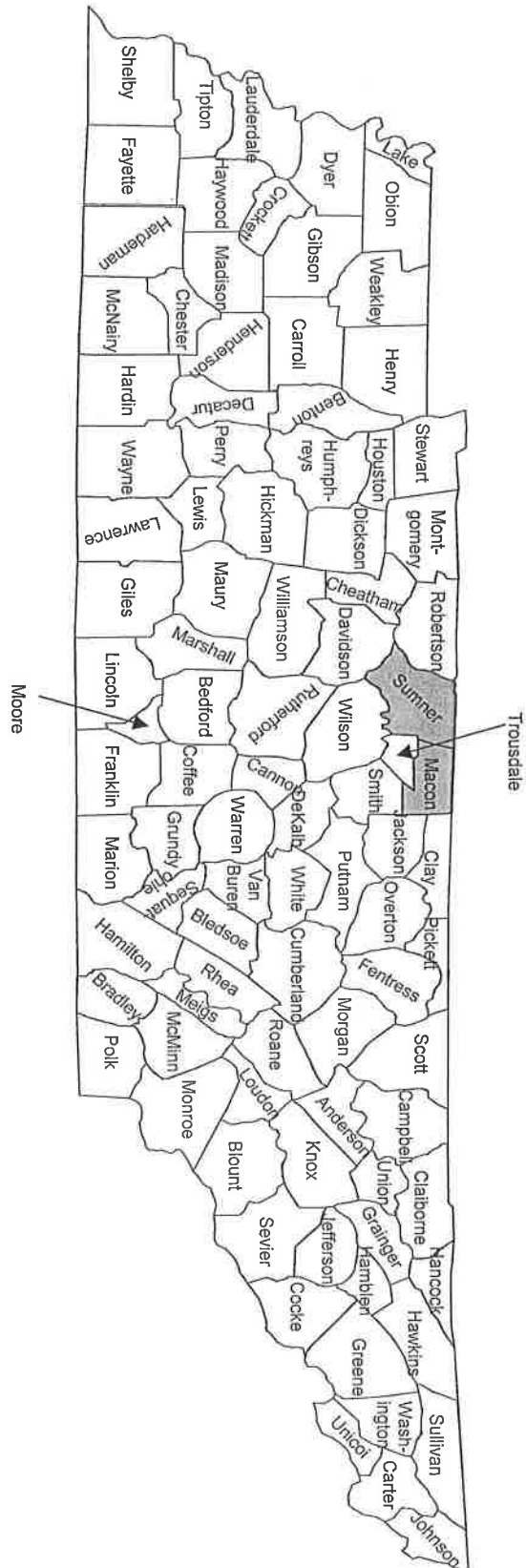
03/07/2014 - C.O.N. SUBMITTAL - NOT FOR CONSTRUCTION

HINSON MILLER KICKIRILLO ARCHITECTS PLLC

TENANT BUILD-OUT - 9,150 SF
ADDITION - 1,570 SF
TOTAL DEPT SF = 10,720 SF

Attachment C, Need - 3

Service Area Map



Attachment C, Need – 4.A.(1)

Demographic Information

State & County QuickFacts

Sumner County, Tennessee

People QuickFacts	Sumner	
	County	Tennessee
Population, 2013 estimate	168,888	6,495,978
Population, 2012 estimate	165,927	6,454,914
Population, 2010 (April 1) estimates base	160,645	6,346,113
Population, percent change, April 1, 2010 to July 1, 2013	5.1%	2.4%
Population, percent change, April 1, 2010 to July 1, 2012	3.3%	1.7%
Population, 2010	160,645	6,346,105
Persons under 5 years, percent, 2012	6.2%	6.3%
Persons under 18 years, percent, 2012	24.6%	23.1%
Persons 65 years and over, percent, 2012	13.8%	14.2%
Female persons, percent, 2012	51.2%	51.2%
White alone, percent, 2012 (a)	90.1%	79.3%
Black or African American alone, percent, 2012 (a)	6.7%	17.0%
American Indian and Alaska Native alone, percent, 2012 (a)	0.3%	0.4%
Asian alone, percent, 2012 (a)	1.2%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	0.1%	0.1%
Two or More Races, percent, 2012	1.6%	1.6%
Hispanic or Latino, percent, 2012 (b)	4.1%	4.8%
White alone, not Hispanic or Latino, percent, 2012	86.5%	75.1%
Living in same house 1 year & over, percent, 2008-2012	83.7%	84.4%
Foreign born persons, percent, 2008-2012	3.4%	4.5%
Language other than English spoken at home, pct age 5+, 2008-2012	5.4%	6.6%
High school graduate or higher, percent of persons age 25+, 2008-2012	87.0%	83.9%
Bachelor's degree or higher, percent of persons age 25+, 2008-2012	23.5%	23.5%
Veterans, 2008-2012	13,277	493,980
Mean travel time to work (minutes), workers age 16+, 2008-2012	27.4	24.1
Housing units, 2012	66,765	2,834,620
Homeownership rate, 2008-2012	72.7%	68.4%
Housing units in multi-unit structures, percent, 2008-2012	15.2%	18.2%
Median value of owner-occupied housing units, 2008-2012	\$175,500	\$138,700
Households, 2008-2012	60,529	2,468,841
Persons per household, 2008-2012	2.64	2.51
Per capita money income in past 12 months (2012 dollars), 2008-2012	\$27,823	\$24,294
Median household income, 2008-2012	\$55,560	\$44,140
Persons below poverty level, percent, 2008-2012	9.8%	17.3%
Business QuickFacts	Sumner	
	County	Tennessee
Private nonfarm establishments, 2011	2,833	129,489 ¹
Private nonfarm employment, 2011	36,154	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	0.9%	1.6% ¹
Nonemployer establishments, 2011	13,447	473,451
Total number of firms, 2007	15,402	545,348
Black-owned firms, percent, 2007	3.2%	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	S	0.5%
Asian-owned firms, percent, 2007	S	2.0%
Native Hawaiian and Other Pacific Islander-owned firms, percent, 2007	F	0.1%

64

Hispanic-owned firms, percent, 2007	1.2%	1.6%
Women-owned firms, percent, 2007	24.2%	25.9%
Manufacturers shipments, 2007 (\$1000)	1,741,400	140,447,760
Merchant wholesaler sales, 2007 (\$1000)	1,634,893	80,116,528
Retail sales, 2007 (\$1000)	1,300,149	77,547,291
Retail sales per capita, 2007	\$8,521	\$12,563
Accommodation and food services sales, 2007 (\$1000)	155,496	10,626,759
Building permits, 2012	592	20,147

Geography QuickFacts	Sumner	
	County	Tennessee
Land area in square miles, 2010	529.45	41,234.90
Persons per square mile, 2010	303.4	153.9
FIPS Code	165	47
Metropolitan or Micropolitan Statistical Area	Nashville-- Davidson-- Murfreesboro --Franklin, TN Metro Area	

1: Includes data not distributed by county.

(a) Includes persons reporting only one race.

(b) Hispanics may be of any race, so also are included in applicable race categories.

D: Suppressed to avoid disclosure of confidential information

F: Fewer than 25 firms

FN: Footnote on this item for this area in place of data

NA: Not available

S: Suppressed; does not meet publication standards

X: Not applicable

Z: Value greater than zero but less than half unit of measure shown

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits
Last Revised: Thursday, 27-Mar-2014 09:57:50 EDT

People

Business

Geography

Data

Research

Newsroom

Search

Go

State & County QuickFacts

Macon County, Tennessee

People QuickFacts	Macon	
	County	Tennessee
Population, 2013 estimate	22,701	6,495,978
Population, 2012 estimate	22,531	6,454,914
Population, 2010 (April 1) estimates base	22,248	6,346,113
Population, percent change, April 1, 2010 to July 1, 2013	2.0%	2.4%
Population, percent change, April 1, 2010 to July 1, 2012	1.3%	1.7%
Population, 2010	22,248	6,346,105
Persons under 5 years, percent, 2012	7.0%	6.3%
Persons under 18 years, percent, 2012	24.9%	23.1%
Persons 65 years and over, percent, 2012	14.9%	14.2%
Female persons, percent, 2012	50.9%	51.2%
White alone, percent, 2012 (a)	97.5%	79.3%
Black or African American alone, percent, 2012 (a)	0.6%	17.0%
American Indian and Alaska Native alone, percent, 2012 (a)	0.7%	0.4%
Asian alone, percent, 2012 (a)	0.3%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	Z	0.1%
Two or More Races, percent, 2012	0.9%	1.6%
Hispanic or Latino, percent, 2012 (b)	4.7%	4.8%
White alone, not Hispanic or Latino, percent, 2012	93.5%	75.1%
Living in same house 1 year & over, percent, 2008-2012	84.9%	84.4%
Foreign born persons, percent, 2008-2012	4.0%	4.5%
Language other than English spoken at home, pct age 5+, 2008-2012	4.2%	6.6%
High school graduate or higher, percent of persons age 25+, 2008-2012	75.1%	83.9%
Bachelor's degree or higher, percent of persons age 25+, 2008-2012	8.5%	23.5%
Veterans, 2008-2012	1,309	493,980
Mean travel time to work (minutes), workers age 16+, 2008-2012	29.8	24.1
Housing units, 2012	9,932	2,834,620
Homeownership rate, 2008-2012	72.8%	68.4%
Housing units in multi-unit structures, percent, 2008-2012	8.9%	18.2%
Median value of owner-occupied housing units, 2008-2012	\$91,800	\$138,700
Households, 2008-2012	8,422	2,468,841
Persons per household, 2008-2012	2.61	2.51
Per capita money income in past 12 months (2012 dollars), 2008-2012	\$17,666	\$24,294
Median household income, 2008-2012	\$35,452	\$44,140
Persons below poverty level, percent, 2008-2012	23.5%	17.3%
Business QuickFacts	Macon	
	County	Tennessee
Private nonfarm establishments, 2011	328	129,489 ¹
Private nonfarm employment, 2011	3,297	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	0.5%	1.6% ¹
Nonemployer establishments, 2011	1,655	473,451
Total number of firms, 2007	S	545,348
Black-owned firms, percent, 2007	S	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	S	0.5%
Asian-owned firms, percent, 2007	S	2.0%
Native Hawaiian and Other Pacific Islander-owned firms, percent, 2007	S	0.1%

66

Hispanic-owned firms, percent, 2007	S	1.6%
Women-owned firms, percent, 2007	S	25.9%
Manufacturers shipments, 2007 (\$1000)	D	140,447,760
Merchant wholesaler sales, 2007 (\$1000)	30,350	80,116,528
Retail sales, 2007 (\$1000)	167,327	77,547,291
Retail sales per capita, 2007	\$7,713	\$12,563
Accommodation and food services sales, 2007 (\$1000)	11,896	10,626,759
Building permits, 2012	15	20,147

Geography QuickFacts	Macon	
	County	Tennessee
Land area in square miles, 2010	307.14	41,234.90
Persons per square mile, 2010	72.4	153.9
FIPS Code	111	47
Metropolitan or Micropolitan Statistical Area	Nashville-- Davidson-- Murfreesboro --Franklin, TN Metro Area	

1: Includes data not distributed by county.

(a) Includes persons reporting only one race.

(b) Hispanics may be of any race, so also are included in applicable race categories.

D: Suppressed to avoid disclosure of confidential information

F: Fewer than 25 firms

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NA: Not available

S: Suppressed; does not meet publication standards

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Z: Value greater than zero but less than half unit of measure shown

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits
Last Revised: Thursday, 27-Mar-2014 09:57:48 EDT

Attachment C, Economic Feasibility – 1

Architect Letter



**HINSON
MILLER
KICKIRILLO**
ARCHITECTS PLLC

March 7, 2014

Ms. Melanie Hill
Executive Director
State of Tennessee
Health Services and Development Agency
500 Deadrick Street, Suite 850
Nashville, TN 37243

RE: Sumner Regional Medical Center-Sumner Station
Linear Accelerator Relocation – Verification of Construction Cost

Dear Ms. Hill:

We have reviewed the construction cost developed for the linear accelerator relocation to the Sumner Station facility. The construction cost of \$3,543,000.00 is based on 9,150 square feet of interior build-out construction, and 1,570 square feet of building addition that will house the relocated linear accelerator. The project also includes site improvements (parking/landscaping) and new entrance canopy.

It is our professional opinion that the construction cost proposed which equates to \$330.50 per square foot is consistent with historical data based on our experience with similar type projects. It is important to note, that our opinion is based on normal market conditions, price escalation, etc.

The project will be developed under the current codes and standards enforced by the State of Tennessee as follows:

2006 International Building Code/2006 International Mechanical Code/2006 International Plumbing Code
2006 International Gas Code
2005 National Electrical Code
2006 NFPA 1, excluding NFPA 5000
2006 NFPA 101, Life Safety Code
2010 FGI Guidelines for the Design and Construction of Health Care Facilities
2002 North Carolina Accessibility Code with 2004 Amendments/2010 Americans with Disabilities Act (ADA)

Sincerely,

HINSON MILLER KICKIRILLO ARCHITECTS PLLC

Donald C. Miller, NCARB, AIA – [TN License No. 100019]

Description of construction/renovation of space:

Sumner Regional Medical Center has planned to develop a Radiation Oncology program located at the recently purchased Sumner Station facility in Gallatin, TN. The project includes approximately 10,720 square feet, of which 9,150 will consist of interior build-out construction for the radiation oncology suite, and 1,570 square feet of building addition that will house a relocated linear accelerator. The project will also consist of site improvements providing additional parking and covered entrance adjacent to the radiation oncology suite.

The build-out area of the project will include patient waiting, business office, exam rooms, CT/Simulator room, doctor's offices and other support spaces making up the radiation oncology suite. The building addition will be the vault housing the linear accelerator.

The construction will include site improvements, concrete slabs/walls/foundations/roof deck, brick veneer, metal stud framing, architectural woodwork, adhered EPDM roofing system, exterior insulation and finish system (EIFS), steel doors/frames, wood doors, drywall, interior finishes, radiation protection, mechanical, plumbing, electrical and fire protection systems.

Describe patient access to the proposed location, including public transportation options, if applicable:

Patient access is provided off of Big Station Camp Boulevard. There is a covered entrance at grade level on the North side of the Sumner Station facility, and a new covered entrance proposed for the West side of this facility that will serve the Radiation Oncology suite. Parking for patients is provided directly adjacent these entrances, including handicapped accessible spaces.

Nashville Metropolitan Transit Authority (MTA) serves Gallatin, but not direct service to the Sumner Station facility. Mid-Cumberland Human Resources Agency RTS Public Transit and taxi services are services that can provide public transportation to this facility.

Attachment C, Economic Feasibility - 2

Funding Letter

AUG 15 14 AM 11:44

LIFEPOINT

HOSPITALS

August 6, 2014

**Melanie Hill
Executive Director
Tennessee Health Services
And Development Agency
Andrew Jackson, 9th Floor
502 Deaderick Street
Nashville, TN 37243**

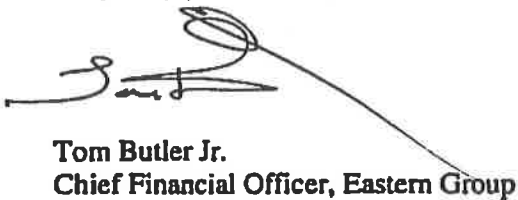
Re: Sumner Regional Medical Center – Certificate of Need to Relocate Radiation Therapy

Dear Ms. Hill:

I am the Chief Financial Officer of LifePoint Hospitals ("LifePoint"), the parent organization of Sumner Regional Medical Center ("SRMC"). This letter confirms that LifePoint has sufficient resources to fund the cost of approximately \$10,667,770 for SMRC's project to relocate its radiation therapy service to its Sumner Station Campus. LifePoint is committed to make these funds available to SMRC.

Thank you for your attention to this matter.

Very truly yours,



**Tom Butler Jr.
Chief Financial Officer, Eastern Group**

330 Seven Springs Way, Brentwood, Tennessee 37027

Phone 615.920.7000

LIFEPOINTHOSPITALS.COM

Attachment C, Economic Feasibility - 9

Financial Statement



INCOME STATEMENT

16750 - SUMNER REGIONAL MEDICAL CENTER

LPNT GROUP OPERATIONS
EASTERN GROUP
HIGHTPOINT MARKET

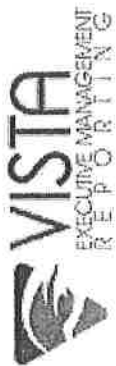
CURRENT MONTH				MED/SURG				YEAR-TO-DATE			
ACTUAL	BUDGET	\$Dollar	PCT%	December 2013	ACTUAL	BUDGET	\$Dollar	PCT%	LAST YEAR	\$Dollar	PCT%
2,829,850	3,372,581	(542,731)	-16.09%	3,105,617	(275,767)	36,491,168	(1,073,449)	-2.86%	32,814,458	3,676,710	11.20%
18,427,906	16,340,537	2,087,369	12.77%	15,611,025	2,816,881	201,034,129	16,667,501	9.04%	155,612,894	45,421,235	29.19%
21,257,756	19,713,118	1,544,638	7.84%	18,716,842	2,541,114	237,525,297	15,594,052	7.03%	188,427,352	49,097,945	26.06%
21,380,922	21,766,928	(386,006)	-1.77%	20,117,736	1,263,186	260,343,510	2,453,422	0.95%	228,705,917	31,637,593	13.83%
42,638,678	41,480,048	1,158,632	2.79%	38,834,378	3,804,300	497,868,807	18,047,474	3.76%	417,133,269	80,735,538	19.35%
77,191	185,043	(107,852)	-58.28%	150,081	(72,890)	1,054,733	(1,165,783)	-52.50%	2,145,286	(1,090,553)	-50.83%
42,715,869	41,665,089	1,050,780	2.52%	38,984,459	3,731,410	498,923,540	16,881,691	3.50%	419,278,555	79,644,985	19.00%
Deductions											
8,496,527	11,160,913	(2,664,386)	-23.87%	10,552,007	(2,055,480)	123,737,102	(4,247,411)	-3.32%	107,990,254	15,748,848	14.58%
(184,146)	(344,154)	160,008	-46.49%	(284,229)	100,083	(3,748,716)	432,345	-10.34%	(4,113,520)	364,804	-8.87%
219,151	142,488	76,663	53.80%	99,200	119,951	1,964,095	273,159	16.15%	1,568,810	395,285	25.20%
0	0	0	0.00%	0	0	264,792	0	0.00%	666,301	(401,509)	-60.26%
18,220,310	16,998,216	1,222,094	7.19%	15,243,724	2,976,586	209,495,957	12,307,504	6.24%	166,410,025	43,085,932	25.89%
437,639	889,733	(452,094)	-50.81%	600,697	(163,058)	9,236,723	(884,564)	-8.74%	8,345,188	891,535	10.68%
3,859,313	1,277,517	2,581,796	202.09%	1,508,286	2,351,027	14,785,997	4,638,950	31.37%	14,155,996	5,266,951	37.22%
2,107,248	1,890,675	216,573	11.45%	1,856,843	250,405	21,870,425	2,667,576	12.20%	18,845,556	5,692,445	30.21%
33,156,042	32,015,388	1,140,654	3.56%	29,576,528	3,579,514	384,912,901	15,452,351	4.18%	313,868,610	71,044,291	22.64%
9,559,827	9,649,701	(89,874)	-0.93%	9,407,931	151,896	114,010,639	1,429,340	1.27%	105,409,945	8,600,694	8.16%
Operating Expenses											
3,461,267	3,473,375	(12,108)	-0.35%	3,312,226	149,041	40,055,155	2,169,872	5.73%	37,563,831	2,491,324	6.63%
8,859	16,149	(7,290)	-45.14%	9,042	(183)	426,239	233,407	121.04%	261,472	164,767	63.09%
641,324	780,382	(139,058)	-17.82%	500,848	140,476	8,215,459	(802,934)	-8.90%	8,170,297	45,162	0.55%
1,458,447	1,638,049	(179,602)	-10.96%	1,299,252	159,195	17,116,174	(1,860,351)	-9.80%	16,661,958	454,216	2.73%
300,199	215,245	84,954	39.47%	237,764	62,435	3,471,629	951,689	37.77%	2,597,496	874,133	33.65%
337,850	570,198	(232,348)	-40.75%	482,503	(144,653)	5,291,202	(26,008)	-0.49%	5,323,282	(32,080)	-0.60%
315,407	300,117	15,290	5.09%	290,265	25,142	3,853,438	288,209	8.08%	3,484,728	368,710	10.58%
(1,922,248)	(1,053)	(1,921,195)	182449.67%	13,057	(1,935,305)	(1,225,122)	(1,213,275)	10241.20%	170,483	(1,395,605)	-818.62%
216,320	218,216	(1,896)	-0.87%	216,480	(160)	2,665,374	74,158	2.86%	2,583,819	81,555	3.16%
39,739	63,074	(23,335)	-37.00%	5,809	33,930	603,498	(148,955)	-19.80%	842,292	(238,794)	-28.35%
0	0	0	0.00%	0	0	0	0	0.00%	0	0	0.00%
507,624	491,984	15,640	3.18%	469,535	38,089	5,960,491	44,603	0.75%	5,419,605	540,886	9.98%
298,430	305,506	(7,076)	-2.32%	241,241	57,189	2,359,656	(438,271)	-15.66%	2,757,053	(397,397)	-14.41%
5,663,218	8,071,242	(2,408,024)	-29.83%	7,078,022	(1,414,804)	88,793,193	(727,856)	-0.81%	85,836,316	2,956,877	3.44%
3,896,609	1,578,459	2,318,150	146.86%	2,329,909	1,566,700	25,217,446	2,157,196	9.35%	19,573,629	5,643,817	28.83%
Capital and Other Costs											
664,830	599,976	64,854	10.81%	762,907	(98,077)	8,408,161	404,687	5.06%	9,640,114	(1,231,953)	-12.78%
0	0	0	0.00%	0	0	0	0	0.00%	0	0	0.00%
0	0	0	0.00%	0	0	0	0	0.00%	0	0	0.00%
126,417	148,941	(22,524)	-15.12%	152,808	(26,391)	1,754,724	(89,014)	-4.83%	1,898,193	(143,469)	-7.56%
367,295	367,295	0	0.00%	340,830	26,465	4,407,540	4,407,540	0.00%	4,089,960	317,580	7.76%
0	0	0	0.00%	0	0	0	0	0.00%	0	0	0.00%
1,158,542	1,116,212	42,330	3.79%	1,256,545	(98,003)	14,570,425	315,673	2.21%	15,628,267	(1,057,842)	-6.77%
2,738,067	462,247	2,275,820	492.34%	1,073,364	1,664,703	10,647,021	1,841,523	20.91%	3,945,362	6,701,659	169.86%
Tax on Income											
0	0	0	0.00%	0	0	0	0	0.00%	0	0	0.00%
0	0	0	0.00%	0	0	0	0	0.00%	0	0	0.00%
0	0	0	0.00%	0	0	0	0	0.00%	0	0	0.00%
2,738,067	462,247	2,275,820	492.34%	1,073,364	1,664,703	10,647,021	1,841,523	20.91%	3,945,362	6,701,659	169.86%



BALANCE SHEET 16750 - SUMNER REGIONAL MEDICAL CENTER

LPNT GROUP OPERATIONS
EASTERN GROUP
HIGHTPOINT MARKET

CURRENT MONTH		December 2013	
BEGIN	CHANGE	Balance Sheet	
		BEGIN	ENDING
Current Assets			
CASH & CASH EQUIVALENTS	-193,037	503,111	-996,299
MARKETABLE SECURITIES	0	0	0
Patient Accounts Receivables			
PATIENT RECEIVABLES	-557,355	30,754,157	36,534,227
LESS ALLOW FOR GOVT RECEIVABLE	0	0	0
LESS ALLOWS - BAD DEBT	683,086	-14,585,007	-17,667,053
NET PATIENT RECEIVABLES	125,731	16,169,150	18,867,174
Final Settlements			
DUE TO/FROM GOVT PROGRAMS	0	-618,647	-586,317
ALLOWES DUE GOVT PROGRAMS	0	-36,652	-38,444
NET FINAL SETTLEMENTS	0	-655,299	-624,761
NET ACCOUNTS RECEIVABLE	125,731	15,513,851	18,242,413
INVENTORIES	14,406	3,043,772	3,060,038
PREPAID EXPENSES	1,182,270	397,631	1,841,590
OTHER RECEIVABLES	-14,955	78,582	343,213
TOTAL CURRENT ASSETS	1,114,415	19,536,947	22,490,955
Property, Plant, Equipment			
LAND	2,702,700	4,170,000	6,872,700
BLDGs AND IMPROVEMENT	15,365,552	99,024,614	114,390,166
EQUIPMENT OWNED	350,572	28,467,849	27,861,873
EQUIPMENT CAPITAL LEASES	0	0	0
CONSTRUCTION IN PROGRESS	34,888	6,111	71,483
GROSS PP&E	18,453,712	131,668,574	149,196,222
LESS ACCUMULATED DEPRECIATION	-652,739	-21,054,579	-27,788,003
NET PP&E	17,800,973	110,613,995	121,408,219
Other Assets			
INVESTMENTS	0	0	0
NOTES RECEIVABLES	0	0	0
INTANGIBLE ASSETS - NET	-53,712	26,015,572	26,363,719
INVESTMENT IN SUBSIDIARIES	0	0	0
OTHER ASSETS	-65,313	65,413	100
TOTAL OTHER ASSETS	-119,025	26,080,985	26,363,819
GRAND TOTAL ASSETS	18,796,363	156,231,927	170,262,993



BALANCE SHEET **16750 - SUMNER REGIONAL MEDICAL CENTER**

LPNT GROUP OPERATIONS
 EASTERN GROUP
 HIGHTPOINT MARKET

CURRENT MONTH		December 2013	
BEGIN	CHANGE	Liabilities & Equity	
ENDING			YEAR-TO-DATE
			BEGIN CHANGE ENDING
Current Liabilities			
3,058,995	-536,652	ACCOUNTS PAYABLE	1,880,744 641,599 2,522,343
2,493,424	359,005	ACCRUED SALARIES	2,631,521 220,908 2,852,429
1,111,487	609,199	ACCRUED EXPENSES	2,289,129 -568,443 1,720,686
0	0	ACCRUED INTEREST	0 0 0
0	0	DISTRIBUTIONS PAYABLE	0 0 0
318,800	10,825	CURR PORT - LONG TERM DEBT	216,420 113,205 329,625
873,872	-315,830	OTHER CURRENT LIABILITIES	936,353 -378,311 558,042
0	0	INCOME TAXES PAYABLE	0 0 0
7,856,578	126,547	TOTAL CURRENT LIABILITIES	7,954,167 28,958 7,983,125
Long Term Debt			
3,703,996	-31,521	CAPITALIZED LEASES	4,002,101 -329,626 3,672,475
121,897,188	18,113,315	INTERCOMPANY DEBT	134,376,671 5,633,832 140,010,503
0	0	OTHER LONG TERM DEBT	0 0 0
125,601,184	18,081,794	TOTAL LONG TERM DEBT	138,378,772 5,304,206 143,682,978
Deferred Credits and Other Liabilities			
0	0	PROF LIABILITY RISK RESERVES	0 0 0
0	0	DEFERRED INCOME TAXES	0 0 0
2,172,172	-2,150,045	LONG TERM OBLIGATIONS	1,971,250 -1,949,123 22,127
2,172,172	-2,150,045	TOTAL OTHER LIAB. AND DEF.	1,971,250 -1,949,123 22,127
Equity			
0	0	COMMON STOCK - PAR VALUE	3,945,365 -3,945,365 0
0	0	CAPITAL IN EXCESS OF PAR VALUE	0 0 0
7,927,742	0	RETAINED EARNINGS - START YEAR	3,945,369 7,927,742
7,908,954	2,738,067	NET INCOME CURRENT YEAR	0 10,647,021 10,647,021
0	0	DISTRIBUTIONS	0 0 0
0	0	OTHER EQUITY	0 0 0
15,836,696	2,738,067	TOTAL EQUITY	7,927,738 10,647,025 18,574,763
151,466,630	18,796,363	TOTAL LIABILITIES AND EQUITY	156,231,927 14,031,066 170,262,993

**Attachment C, Contribution to the
Orderly Development of Health Care - 1**

Managed Care Contracts

HighPoint Health System Affiliates

Insurance Contract Name and Network Plan Types

Last Updated 1-2014

HighPoint Health System Affiliates Insurance Contract Name and Network Plan Types Last Updated 1-2014	Summer Regional Medical Center		Trousdale Medical Center	Riverview Regional Medical Center		Summer Homecare and Hospice			
	Hospital	Summer Inpatient Rehab Unit	Hospital	Hospital	Hospital	Carthage	Gallatin	Goodlettsville	Hospice
AmeriChoice - (United Healthcare Community Plan as of 01/01/11)	●		◆ No Swing	✱ No Swing		■	■	■	■
AmeriGroup - Community Care	●		◆ No Swing	✱ No Swing		■	■	■	■
Aetna	●	●	◆	✱		■	■	■	■
BeechStreet	●	●	◆	✱		■	■	■	■
Blue Network P (Blue Preferred)	●	●	◆ No Swing	✱ No Swing		■	■	■	■
Blue Network S (Blue Select)	●	●	◆ No Swing	✱ No Swing		■	■	■	■
Blue Network V (CoverTN)	●	●	◆ No Swing	✱ No Swing		■	■	■	■
BlueCare / TennCare Select	●		◆ No Swing	✱ No Swing		■	■	■	■
Center Care PPO	●	●	◆	✱		■	■	■	■
Cigna	●	●	◆	✱		■	■	■	■
Corvel Work Comp	●	●	◆	✱		■	■	■	■
First Health (Includes CCN PPO)	●	●	◆	✱		■	■	■	■
Great West Healthcare	●	●	◆	✱		■	■	■	■
HealthScope Benefits (Access the CenterCare Network in TN)	●	●	◆	✱		■	■	■	■
HealthSpring Commercial Plans	●	●	◆	✱		■	■	■	■
HealthSpring Medicare Advantage Plans	●	●	◆	✱		■	■	■	■
Humana ChoiceCare Network	●	●	◆	✱		■	■	■	■
Humana Medicare PPO	●	●	◆	✱		■	■	■	■
MultiPlan	●	●	◆	✱		■	■	■	■
NovaNet	●	●	◆	✱		■	■	■	■
PPO USA (GEHA)	●	●	◆	✱		■	■	■	■
pboNext	●	●	◆	✱		■	■	■	■
Prime Health Services	●	●	◆	✱		■	■	■	■
Private Health Care Systems (PHCS)	●	●	◆	✱		■	■	■	■
Principal Edge Network	●	●	◆	✱		■	■	■	■
Provider Networks of America (ProNet access Signature PPO in TN)	●	●	◆	✱		■	■	■	■
Signature Health Alliance	●	●	◆	✱		■	■	■	■
Synergy Health Network	●	●	◆	✱		■	■	■	■
TriCare Military Services (Humana Prime Plan)	●	●	◆	✱		■	■	■	■
United HealthCare	●	●	◆	✱		■	■	■	■
USA Health Network (USA MCO)	●	●	◆	✱		■	■	■	■
Windsor	●	●	◆	✱		■	■	■	■
Windsor - Geopsych	●	●	◆	✱		■	■	■	■
Medicare Advantage Plans PFFS-Do Not Require Contracts or Networks all facilities can treat these patients.	●	●	◆	✱		■	■	■	■
Private Fee For Service	●	●	◆	✱		■	■	■	■

**Attachment C, Contribution to the
Orderly Development of Health Care – 7(c)**

License

Board for Licensing Health Care Facilities



State of Tennessee

DEPARTMENT OF HEALTH

No. of Beds 0155
0000000116

This is to certify, that a license is hereby granted by the State Department of Health to

SUMNER REGIONAL MEDICAL CENTER, LLC
to conduct and maintain a

Hospital

SUMNER REGIONAL MEDICAL CENTER

Located at

555 HARTSVILLE PIKE, GALLATIN

County of

SUMNER

Tennessee.

This license shall expire JUNE 25 , 2015 , *and is subject*

to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable, and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the State Department of Health issued thereunder.

We Witness Whereof, we have hereunto set our hand and seal of the State this 25TH *day of* JUNE , 2014 .

GENERAL HOSPITAL
PEDIATRIC GENERAL HOSPITAL

In the Distinct Category(ies) of:



By Justin J. Davison, MPH
DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

By John J. Dyer, MD
COMMISSIONER

**Attachment C, Contribution to the
Orderly Development of Health Care – 7(d)**

Survey and POC



RECEIVED

OCT 18 2006

JS

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
BUREAU OF HEALTH LICENSURE AND REGULATION
MIDDLE TENNESSEE REGIONAL OFFICE
710 HART LANE, 1ST FLOOR
NASHVILLE, TENNESSEE 37247-0530
PHONE (615) 650-7100
FAX (615) 650-7101

October 17, 2006

R. Bruce James, Administrator
Sumner Regional Medical Center
555 Hartsville Pike
Gallatin, TN 37066

Dear Mr. James:

Enclosed is the statement of deficiencies developed as a result of the state licensure survey completed on October 11, 2006 at Sumner Regional Medical Center.

Please provide us with documentation to describe how and when these deficiencies will be corrected. This information should be received in our office within ten (10) calendar days after receipt of this letter. We are requesting that you assure correction of the cited deficiencies no later than sixty (60) days from the date of the survey. A follow-up visit may be conducted, if your allegation of correction is reasonable and convincing. Failure to provide an acceptable plan of correction could result in a referral to the Board of Licensing Health Care Facilities for whatever action they deem appropriate.

In order for your Plan of Correction (PoC) to be acceptable, it should address the following:

1. How you will correct the deficiency;
2. Who will be responsible for correcting the deficiency;
3. The date the deficiency will be corrected; and
4. How you will prevent the same deficiency from happening again.

Should you have any questions, or if there is any way this office may be of assistance, please do not hesitate to call.

Sincerely,

A handwritten signature in cursive script that reads "Nina Monroe".

Nina Monroe, Regional Administrator
Middle Tennessee Regional Office

Enclosure
NM/dv

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 404	<p>1200-8-1-.04 (4) Administration</p> <p>(4) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A hospital which violates a required policy also violates the rule and regulation establishing the requirement.</p> <p>This Statute is not met as evidenced by: Based on observation interview and record review it was determined the facility failed to adhere to the provisions of the facility's policies labeled "Intravascular Devices" and "Medication Administration".</p> <p>The findings included:</p> <p>Observation of one random patient in the facilities Intensive Care Unit on 10/11/06 at 10:40 AM in room 6 revealed a Patient whom had two Intravenous Dressings. One dressing was covering a Triple Lumen Catheter that was located on the Patients right subclavian area of the anterior chest and the other Intravenous access was located in the patients right arm antecubital area. Observation of the dressings revealed there was no documentation on the transparent dressings of either site.</p> <p>Record review Patient #27 of 37 sampled Patients revealed documentation by the Medical Doctor on 10/10/06 at 1500 in the Physicians Progress notes indicating the Triple Lumen Catheter was placed in Patient #27 on 10/10/06. Confirmation was made with the Intensive Care Unit, Care Coordinator of these findings on 10/11/06 at 10:50 AM. The policy labeled</p>	H 404		

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

STATE FORM

5599

Y0LZ11

If continuation sheet 1 of 1

PRINTED: 10/16/2006
FORM APPROVED

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 404	<p>Continued From page 1</p> <p>"Intravascular Devices" reads on page 2 of the policy "I. Documentation 1. Record date and time of catheter insertion on label provided in the IV start kit and attach to IV dressing."</p> <p>Tour of the facilities operating room on 10/10/06 at 11:00 AM in room 1 revealed 22 milliliters of a white liquid in a 30 milliliter syringe located on top of an anesthesia cart unattended. Further observation revealed the cart was unlocked. There was no label noted on the syringe containing the 22 milliliters of the white liquid. Interview with an anesthesiologist in the surgery hallway on 10/10/06 at 11:05 reports "We don't label the propofol." Confirmation was made with the Surgery Director on 10/10/06 at 11:06 AM that the medication should be labeled.</p> <p>Review of the facilities policy labeled "Medication Administration" reads under the section labeled Procedure: "12. Medications and solutions both on and off the sterile field should be labeled even if there is only one medication being used. 13. Labeling occurs when any medication or solution is transferred from the original packaging to another. 14. Labels should include drug name, strength, amount, if not used within 24 hours, and expiration time when expiration occurs in less than 24 hours."</p> <p>Observation on 10/10/06 at 3:15 PM during an interview with Patient # 37 of the 37 sampled Patients revealed a right Port-A-Cath central line intravenous dressing with no date and signature. The findings were confirmed in an interview with the 4th Floor charge nurse at this time. Medical record review on 10/10/06 at 3:20 PM revealed a needle and dressing change documented in the</p>	H 404			

Division of Health Care Facilities
STATE FORM

8899

Y0LZ11

If continuation sheet 2 of 12

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 404	Continued From page 2 nursing notes at 8:45 AM on 10/10/06. The facility policy to date and initial all intravenous dressings was confirmed on 10/10/06 at 3:20 PM by the Director of Medical/Surgical and the 4th Floor charge nurse. Review of the facility policy entitled, "Intravascular Devices" revealed that documentation should include recording the date and time of the catheter insertion on the label provided in the Intravenous start kit and attach to the intravenous dressing.	H 404			
H 647	1200-8-1-.06 (3)(i)4. Basic Hospital Functions (3) Infection Control. (i) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including: 4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies; This Statute is not met as evidenced by: Based on observation and interview it was determined the facility failed to ensure the sterility and package integrity of several random items found in the facilities clinical areas that were out of date as per the manufacturer guidelines. The findings included:	H 647			

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 647	<p>Continued From page 3</p> <p>During tour in the Intensive Care Unit 10/11/06 at 10:55 AM in the "Line Cart" located in front of the Intensive Care Units Nursing Station revealed a package in the third drawer in the cart that contained a package labeled "Scrub Care Preoperative Skin Care Prep Tray" that had an expiration date printed on the package of June 2006. Confirmation was made with the Intensive Care Unit/ Care Coordinator at 11:00 AM that the package was out of date.</p> <p>Observation during a tour of the newborn nursery on 10/11/06 at 12:30 PM revealed expired supply items in the third drawer of the emergency supply cabinet</p> <p>One 18 gauge Insyte Autoguard chest tube needle with an expiration date of January 2004.</p> <p>Three 14 gauge Insyte Autoguard chest tube needles with an expiration date of March 2005.</p> <p>Three 16 gauge Insyte Autoguard chest tube needles with an expiration date of January 2006.</p> <p>The above findings were confirmed with the Director of Women's Services and the Accreditation Coordinator on 10/11/06 at 1:00 PM.</p> <p>Review of the facility policy entitled, "Shelf Life of Sterile Supplies" revealed that all expiration dated packages of purchased sterile supplies must be checked and rotated weekly.</p>	H 647			
H 665	<p>1200-8-1-.06 (3)(o) Basic Hospital Functions</p> <p>(3) Infection Control.</p> <p>(o) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.</p>	H 665			

Division of Health Care Facilities
STATE FORM

6599

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If continuation sheet 4 of 12

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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H 665	<p>Continued From page 4</p> <p>This Statute is not met as evidenced by: Based on observation and interview, it was determined that the facility failed to provide a clean and sanitary physical environment</p> <p>The findings included:</p> <p>Observation on 10/10/06 at 11:10 AM during a tour of the 4th Floor (West) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator at this time.</p> <p>Observation on 10/10/06 at 2:40 PM during a tour of the 4th Floor (East) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator at this time. Continued tour of this unit at 2:45 PM revealed an empty patient room with an overbed table with dried brown and white matter on the internal compartment. The findings were confirmed with the accreditation coordinator at this time. Continued interview with the accreditation coordinator at this time also revealed that the room was cleaned and available for patient occupancy at the time of the observations.</p> <p>Observation on 10/11/06 at 10:00 AM during a tour of the 2nd Floor (West) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator and the director of the 2nd floor at this time.</p> <p>Observation on 10/11/06 at 10:10 AM during a tour of the 2nd Floor (East) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the</p>	H 665			

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
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H 665	Continued From page 5 patient care coordinator and the director of the 2nd floor at this time. Observation on 10/11/06 at 11:50 AM during a tour of the Labor and Delivery unit kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator and the accreditation coordinator at this time. Continued observation at 11:58 AM revealed a sink in the workroom between the Labor, Delivery, and Recovery room (LDR) #1 and LDR #2 that contained a white container one-half full with a light yellow liquid. The findings were confirmed with the director of women's services at this time and that the container should have been removed after cleaning the room.	H 665			
H 706	1200-8-1-.06 (6)(a) Basic Hospital Functions (6) Pharmaceutical Services. (a) The hospital must have pharmaceutical services that meet the needs of the patients and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. This Statute is not met as evidenced by: Based on observation, interview, and policy review the facility failed to provide Pharmaceutical Services in compliance with approved policies and procedures. The findings included:	H 706			

Division of Health Care Facilities
STATE FORM

6899

YOLZ11

If continuation sheet 6 of 12

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 706	<p>Continued From page 6</p> <p>Observation of the Preoperative Area in the Surgery Department on 10/10/06 at 10:00 AM revealed a refrigerator that contained in the side door compartment a 0.9 % saline solution 500 milliliter clear plastic bag for intravenous infusion with an expiration date that reads "June 06". Confirmation was made with the Director of Surgical Services at 10/10/06 at 10:10 AM.</p> <p>During tour of the Intensive Care Unit on 10/11/06 at 10:55 AM revealed a "Line Cart" located in front of the nurses desk that contained a 1 liter bottle of 0.9% saline solution with an expiration date of February 05. Further observation of the "Line Cart" revealed a 250 milliliter clear plastic bag labeled 5% Dextrose solution for intravenous infusion with an expiration date of January 05. Confirmation was made with the Intensive Care Unit/ Care Coordinator on 10/11/06 at 11:00 AM of the expired items.</p> <p>Review of the facility policy labeled "Outdated or Unusable Drugs (Return to Pharmacy)" Policy Number Rx-036 reads under the section labeled Procedure reads, "1. Whenever unusable or outdated drugs are found in the hospital, they will be returned to the Pharmacy for proper disposal." The facility policy labeled Out-Dated Drugs (Storage and Disposition) Policy Number Rx-037, reads "The Pharmacy stock and all drug storage areas in the hospital are checked monthly for out dated-drugs."</p> <p>Observation on 10/10/06 at 2:35 PM during a tour of the 4th Floor (East) unit clean supply room revealed three 5 liter bags of sterile water for irrigation with an expiration date of September 2006. The findings were confirmed in an</p>	H 706			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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H 706	Continued From page 7 interview with the medical/surgical director at this time. Continued observation of the 4th Floor medication Pyxis system at 2:55 PM revealed a locked medication refrigerator attached to the Pyxis that contained an opened, one-half full bottle of Citrate of Magnesia labeled Room 433B. An interview with the medical/surgical director at 3:05 PM on 10/10/06 revealed that the Patient had been discharged on 8/31/06. Observation on 10/11/06 at 11:40 AM during a tour of the postpartum unit clean supply room revealed the following expired drugs: One liter bag of Dextrose 5% in Water with an expiration date of September 2006. One liter bag of Dextrose 5% in 0.2% Sodium Chloride solution with an expiration date of September 2006. The above findings were confirmed in an interview with the director of women's services at this time.	H 706			
H 714	1200-8-1-.06 (7)(a) Basic Hospital Functions (7) Radiologic Services. (a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. This Statute is not met as evidenced by: Based on observations, interviews, and policy review the facility failed to ensure the safety of	H 714			

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H 714	Continued From page 8 one radiology employee. The findings included: Observations of the Radiology Department on October 11, 2006, revealed a Registered Nurse (RN#1) working in the Computed Tomography Room at 10:00 am, and in the Nuclear Medicine Room at 10:10 am, without a dose/film badge on his/her person. Interview with RN#1, at 10:00 am, on October 11, 2006, revealed the RN worked as a contract employee in Interventional Radiology, and had been employed at the facility for seven weeks. Interview with the Radiology Department Manager at 10:00 am, on October 11, 2006, confirmed RN#1 should have been wearing a dose/film badge. Review of the facility's Radiation Safety Operations Manual revealed all employees requiring dosimetry shall be issued a standard film badge and/or thermoluminescent dosimeter, and the exposure measurements will be recorded and kept on file.	H 714		
H 730	1200-8-1-.06 (9)(b) Basic Hospital Functions (9) Food and Dietetic Services. (b) The hospital must designate a person to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be: 1. A dietitian; or, 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or,	H 730		

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H 730	Continued From page 9 3. A graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian. This Statute is not met as evidenced by: Based on review of employee records and staff interview, it was determined the facility failed to have a qualified food service director. The findings included: Review of the record for the Food Service Director revealed and interview, with this Employee the afternoon of 10/10/06, confirmed, the Employee was not enrolled in or had attended a 90 + hour food service supervision course.	H 730			
H 737	1200-8-1-.06 (9)(g) Basic Hospital Functions (9) Food and Dietetic Services. (g) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to patients with special dietary needs. This Statute is not met as evidenced by: Based on staff interviews, it was determined the facility exceeded the 14 hour lapse between supper and breakfast and did not provide a supplemental meal. The findings included:	H 737			

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H 737	Continued From page 10 Interview with the facility Food Service Director and shift manager, the morning of 10/10/06, confirmed the Supper was served at 4:15 PM and the Breakfast at 7 AM without a supplemental meal between those hours to the patients.	H 737			
H 739	1200-8-1-.06 (9)(I) Basic Hospital Functions (9) Food and Dietetic Services. (i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current "U.S. Public Health Service Food Service Sanitation Manual". This Statute is not met as evidenced by: Based on observation and staff interview, it was determined the dietary department was not maintained in a sanitary manner and cold food exceeded 41 degrees at the trayline. the findings included: Observation during the department tour, at 9:15 AM of 10/10/06, with the Food Service Director present, revealed the following ceiling vents and surrounding ceiling tiles had an accumulation of debris: between the grill and steamer; over the production table and steam jacketed kettle; in the dishroom on the dirty side, clean side and over the 3 compartment sink; by the reach-in refrigerators between the production and catering	H 739			

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H 739	Continued From page 11 sections and outside the diet office. Observation at 9:38 AM revealed the dishes were being processed and the 3 compartment sink was being used in the dishroom. Further observation during the tour revealed four cases of cups were stacked and a case of cup lids were stored on the floor of the paper storeroom. Observation during the mid-day meal trayline revealed a staff member taking and recording the food temperatures at 11:30 AM. Continued observation revealed the milk temperature was 43 degrees and served to the pureed textured diets. Interview, at 11:40 AM, with the shift manager revealed the person taking the temperatures was instructed to remove and replace any foods not in the appropriate temperature ranges.	H 739			

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P 001	1200-8-30 Initial This Statute is met as evidenced by: No deficiencies were cited as a result of the Pediatric Emergency Care Facility Survey completed on October 11, 2006.	P 001			

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

STATE FORM

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING 02 - STATE BUILDING B. WING _____	(X3) DATE SURVEY COMPLETED 10/10/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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H 872	1200-8-1-.08 (2) Building Standards (2) The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to maintain the hospital environment for the safety of both residents and staff as required by the Standard Regulation 1200-8-1-08(2) the NFPA 101, 8.5.5.2; 101, 8.5.5.3. The findings included: On 10-10-2006 at approximately 2:00 PM during inspection within the basement equipment room, observation revealed, there were penetrations in both the ceiling and the wall.	H 872		
H 874	1200-8-1-.08 (4) Building Standards. (4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities, and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are	H 874		

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING 02 - STATE BUILDING B. WING _____		(X3) DATE SURVEY COMPLETED 10/10/2006
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H 874	Continued From page 1 conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to comply with the Regulatory Codes as required by the Standard Regulation 1200-8-1-08(4) and the Standard Building Code- SBC 1403.2.3. The findings included: On 10-10-2006 at approximately 1:45 PM during inspection within the basement area, observation revealed, a steel lintel carrying brick veneer over a doorway was missing. SBC 1403.2.3.	H 874			
H 893	1200-8-1-.08 (23) Building Standards. (23) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor ' s closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection, testing and observation, it was determined, the facility failed to maintain the negative air pressure within soiled areas as required by the Standard Regulation 1200-8-1-08(23) and the NFPA 90A; 90B-4; 101, 19. 5.2.1.	H 893			

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING 02 - STATE BUILDING B. WING _____		(X3) DATE SURVEY COMPLETED 10/10/2006
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H 893	Continued From page 2 The findings Included: On 10-10-2006 at approximately 2:30 PM during inspection within the men's bathroom in the Cath Lab area, testing revealed, the exhaust fan units were not working. Inspection and observation within the Medical Imaging area revealed, the return-air grilles were dusty. Inspection and observation within the elevator equipment room revealed, the exhaust fan unit was dusty. During inspection and observation within the dietary area, observation revealed, both air-return units and exhaust fan grilles were dusty.	H 893			
H 951	1200-8-1-.09 (1) Life Safety (1) Any hospital which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to comply with the applicable building and fire safety regulations as required by the Standard Regulation 1200-8-1-08(1). and the NFPA 10, 1.5.6; 55, 6.6; 70, 240-5; 70, 373-4; 410-56(d).	H 951			

Division of Health Care Facilities

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H 951	<p>Continued From page 3</p> <p>The findings included:</p> <p>On 10-10-2006 at approximately 12:30 PM during inspection within the basement shop area, observation revealed, the portable fire extinguisher was blocked with equipment. That was in violation of the NFPA 10, 1.5.6.</p> <p>Inspection within the storage area of the basement mechanical room revealed three pressurized cylinders which were not secured. Violation of the NFPA 55, 6.6.</p> <p>During inspection within the pain clinic of the Cath Lab area, observation revealed the use of an extension cord. NFPA 70, 240-5.</p> <p>During inspection on the 3rd floor next to the rehab area, observation within the electric panel room revealed, panels TA and TB both had unusual open space under the breakers. Violation of the NFPA 70, 373-4.</p> <p>During inspection within the basement mechanical equipment area, observation revealed a junction box without any cover plate.</p> <p>During inspection within the ceiling space above the east fire doors to the Cath Lab area, observation revealed, there was an open junction box without any cover plate.</p> <p>Inspection above the west fire doors of the Cath Lab revealed open junction box with loose wires. Those were in violation of the NFPA 70, 410-56(d).</p>	H 951		



Administrative Offices

October 24, 2006

Ms. Nina Monroe, Regional Administrator
State of Tennessee Department of Health
Bureau of Health Licensure and Regulation
Middle Tennessee Regional Office
710 Hart Lane, 1st Floor
Nashville, Tennessee 37247-0530

Dear Ms. Monroe:

The following information is provided in response to the recent state licensure survey completed on October 11, 2006 at Sumner Regional Medical Center.

ID Prefix Tag: H 404 1200-8-.04 (4) Administration

How SRMC will correct the deficiency: We will correct "no documentation on the transparent intravenous dressing" by following our policy and recording date and time of catheter insertion on the label provided in the IV starter kit and then attaching it to the IV dressing.

Who at SRMC will be responsible for correcting the deficiency: Director, Med/Surg

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking for this documentation.

How SRMC will correct the deficiency: We will correct failure to label medication and solutions both on and off the sterile field by following our stated policy and further educating our staff and anesthesiologists.

Who at SRMC will be responsible for correcting the deficiency: Director, Surgical Services, and Director Women's Services

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted to ensure compliance with re-education as needed.

How SRMC will correct the deficiency: We will ensure that all anesthesia carts are locked when not in use.

Who at SRMC will be responsible for correcting the deficiency: Director, Surgical Services, and Director Women's Services

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted to ensure compliance with re-education as needed.

How SRMC will correct the deficiency: We will correct "no documentation on the transparent intravenous dressing of Port-A-Cath" by following our policy and recording date and time of catheter insertion on the label provided in the IV starter kit and then attaching it to the IV dressing.

Who at SRMC will be responsible for correcting the deficiency: Director, Med/Surg

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking for this documentation.

ID Prefix Tag: H 647 1200-8-1-.06 (3)(i) 4 Basic Hospital Function

How SRMC will correct the deficiency: We will re-educate stocking personnel on the importance of accuracy of daily checks and ensuring that no items remain in stock after expiration date.

Who at SRMC will be responsible for correcting the deficiency: Director, Material Management

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking at expiration dates to ensure compliance and immediate re-education as required.

ID Prefix Tag: H 665 1200-8-1-.06 (3)(o) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately correct and reeducate environmental services associates on proper cleaning of microwave ovens and bed side tables, and disposal of used cleaning materials.

Who at SRMC will be responsible for correcting the deficiency: Director, Environmental Services

The date the deficiency will be corrected: October 11, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically ensuring these deficiencies remain in compliance.

ID Prefix Tag: H 706 1200-8-1-.06 (6)(a) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately check all supply carts to ensure no expired solutions remain.

Who at SRMC will be responsible for correcting the deficiency: Director, Material Management

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically ensuring that expired items do not exist.

How SRMC will correct the deficiency: We will ensure that all medications belonging to a specific patient are removed when that patient leaves the hospital.

Who at SRMC will be responsible for correcting the deficiency: Director, Pharmacy

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Pyxis units are checked daily by Pharmacy staff. They will ensure this occurs. Spot checks will be conducted on all Pyxis units specifically ensuring that expired items or medications from previous patients do not exist.

ID Prefix Tag: H 714 1200-8-1-.06 (7)(a) Basic Hospital Functions

How SRMC will correct the deficiency: We will make sure that all Radiology Department associates wear a dose/film badge.

Who at SRMC will be responsible for correcting the deficiency: Director, Diagnostic Services

The date the deficiency will be corrected: October 11, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all diagnostic imaging areas specifically ensuring dose/film badges are worn by all associates working in that area.

ID Prefix Tag: H 730 1200-8-1-.06 (9)(b) Basic Hospital Functions

How SRMC will correct the deficiency: We will enroll the Director, Nutritional Service in a 90 hour food service supervisor course and make sure that he completes the course within two years.

Who at SRMC will be responsible for correcting the deficiency: Vice President, Support Services

The date the deficiency will be corrected: No later than October 11, 2008.

How will SRMC prevent the same deficiency from happening again: Vice President, Support Services will ensure that this requirement is added to the current contract as well as any future contracts and then annually reviewed for compliance.

ID Prefix Tag: H 737 1200-8-1-.06 (9)(g) Basic Hospital Functions

How SRMC will correct the deficiency: We will ensure that no more than 14 hours lapse between supper and breakfast.

Who at SRMC will be responsible for correcting the deficiency: Director, Nutritional Services

The date the deficiency will be corrected: November 20, 2006

How will SRMC prevent the same deficiency from happening again: By adjusting meal service hours on the inpatient floors, not exceeding 14 hours becomes the standard. Spot checks will monitor compliance.

ID Prefix Tag: H 739 1200-8-1-.06 (9)(i) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately clean and maintain cleanliness in all areas sited.

Who at SRMC will be responsible for correcting the deficiency: Director, Nutritional Services

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Daily inspections and spot checks. Note: State surveyor re-examined area on October 12, 2006 and verbally expressed her satisfaction with the previous night's cleaning.

How SRMC will correct the deficiency: Closer monitoring of the cold food temperatures in the tray line and meal preparation areas.

Who at SRMC will be responsible for correcting the deficiency: Director, Nutritional Services

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Daily inspections and spot checks.

ID Prefix Tag: H 872 1200-8-1-.08 (2) Building Standards

How SRMC will correct the deficiency: We will seal all penetrations in the wall and ceiling in the basement equipment room.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: November 30, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations as well as the Director, Safety and Security. Spot checks as part of the Environment of Care (JCAHO) continuous readiness.

ID Prefix Tag: H 874 1200-8-1-.08 (4) Building Standards

How SRMC will correct the deficiency: We will install a steel lintel carrying brick veneer over a doorway in the basement area.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: November 30, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations as well as the Director, Safety and Security. Spot checks as part of the Environment of Care (JCAHO) continuous readiness.

ID Prefix Tag: H 893 1200-8-1.08 (23) Building Standards

How SRMC will correct the deficiency: We will repair and clean exhaust fans in the Cath Lab, Medical Imaging, Elevator Equipment room and Dietary areas.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations, Director, Environmental Services, Director Nutritional Services

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again: Increased inspections and spot checks by appropriate Director.

ID Prefix Tag: H 951 1200-8-1-.09 (1) Life Safety

How SRMC will correct the deficiency: We will ensure that all portable fire extinguishers are readily available and not blocked from use.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will ensure that all pressurized cylinders are properly secured.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will remove the extension cord in the Cath Lab and ensure that appropriate electrical outlets are available.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: November 30, 2006

Page 6 of 6
October 24, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will secure the open space under the breakers in electrical panel 3rd Floor, TA and TB.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will cover the junction box in the basement mechanical equipment area.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will cover the junction box in the ceiling space above the east fire doors to the Cath Lab.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will secure the loose wires and cover the junction box above the west fire doors of the Cath Lab.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

Should you have any questions please contact Mr. Fred Levoy at 615 451-5529 or email; Fred.Levoy@Sumner.Org.

Sincerely,



R. Bruce James
Administrator

SUPPLEMENTAL

#1

August 26, 2014

VIA HAND DELIVERY

Jeff Grimm
HSDA Examiner
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Certificate of Need Application CN1408-036
Sumner Regional Medical Center – Relocation of
Linear Accelerator from Main Hospital Campus to Outpatient Campus

Dear Mr. Grimm:

Responses to the questions in your letter dated August 20, 2014, are below. Please let us know if you need additional information.

1. Section A, Applicant Profile, Item 1

Based on HSDA's understanding of the Letter of Intent and review of the property deed for the outpatient campus (proposed site of linear accelerator), it appears that the address of the intended location of the linear accelerator should be indicated here in lieu of the hospital's main campus address. Please confirm by revising this item to reflect the location in an existing building on the hospital's outpatient campus at 225 Big Station Camp Boulevard, Gallatin, TN.

Response: The correct address for the applicant is 555 Hartsville Pike, but a revised page 1 is attached as Attachment 1 to reflect the location of the relocated linear accelerator at Sumner Station.

2. Section A, Applicant Profile, Item 3 and Item 4 (ownership)

Item 3: The registration of the owner with the Tennessee Secretary of State's Office is noted. Please also provide a copy of the Corporate Charter or Partnership Agreement.

*The Pinnacle at Symphony Place
150 3rd Avenue South, Suite 1600
Nashville, TN 37201*

DAN H. ELROD
615.651.6702
dan.elrod@butlersnow.com

T 615.651.6700
F 615.651.6701
www.butlersnow.com

Response: *The Certificate of Formation document for the owner is attached at Attachment 2.*

Item 4: Describe the existing ownership structure of Sumner Regional Medical Center, LLC and identify the members of the LLC with 5% or more ownership interest.

Response: *LifePoint Hospitals, Inc., through intervening subsidiaries that are 100% owned by LifePoint Hospitals, Inc., owns 100% of the interests in Sumner Regional Medical Center, LLC.*

In Section B, page 4 of the application, the applicant states that the parent company (LifePoint Hospitals) operates 10 of 63 hospitals in Tennessee. Please provide the information requested in the HSDA application instructions for this item. At a minimum, please include the name, address, current status of licensure and percentage of ownership for each health care institution identified.

Response: *A list of LifePoint's 10 hospitals located in Tennessee is included at Attachment 2. They are all licensed by the Tennessee Department of Health, and their licenses are in good standing.*

3. Section B, Project Description, Item II.B

Please provide a general description of the "Sumner Station" 25 acre outpatient campus, existing structure(s), size, # floors, age of the physical plant and existing services operated by the hospital on the campus. Please identify the complementing modalities offered on site by the hospital for cancer diagnosis.

In your response, please identify arrangements planned for transporting patients from the main hospital campus to Sumner Station for linear accelerator treatments upon completion of the project (as based on 411 inpatient treatments in 2013).

Response: *The Sumner Station facility was constructed in 2007, and it is a two story building with approximately 95,998 sq. ft. of space. Approximately 11,757 sq. ft. are currently used for outpatient imaging (CT, MRI, ultrasound, mammography and x-ray), and approximately 9,900 sq. ft. are used for outpatient rehabilitation (physical therapy, occupational therapy and speech therapy) and a sports medicine physician. The remaining space will be developed to support the health care needs of the community, including the proposed relocation of radiation therapy and the installation of a PET/CT unit that will be the subject of a certificate of need application to be filed in the near future.*

Inpatient patient will be transported by ambulance from SRMC's main campus to Sumner Station for treatment and back to SRMC's main campus.

4. Section B, Project Description, Item II.D

The applicant notes the need & benefit of a new state of the art linear accelerator unit and continuation of modern radiation therapy services in the community. Please describe the applicant's enhancements pertaining to the development and operation of modern radiation therapy services.

Response: The new linear accelerator will include a feature known as an On-Board Imager® (OBI). The OBI is a digital kilovoltage X-ray tube, attached to the linear accelerator, that allows the physician to view patients undergoing treatment with real time, diagnostic quality images and cone beam CT (CBCT) imaging. OBI makes dynamic targeting image-guided radiation therapy (IGRT) more efficient and convenient. The system delivers improved tumor targeting using high resolution, low dose digital imaging in the treatment room. OBI provides the tools to manage changes in position caused by day-to-day set-up conditions as well as changes in position during a patient's treatment session because of normal respiratory and organ motion. This enables physicians and staff to confidently manage patients and target movement—both before and during treatments. OBI is the latest tool added for radiation treatment of cancer and complements IMRT.

Stereotactic body radiation therapy (SBRT) and stereotactic radiosurgery (SRS) are forms of radiation therapy in which high doses of radiation are delivered using a very precise beam during three to five treatment sessions. It is generally used for smaller, inoperable lesions and metastases in the liver, brain, and lung. This treatment method may eliminate the need for more invasive treatments and reduce treatment time. Because this approach requires precise patient positioning and exact targeting of the beam, the image guidance system uses OBI/CBCT scans to trace the target.

SMRC's current radiation center is equipped with a linear accelerator that is over 18 years old. It treats patients with external beam radiation therapy (EBRT), three dimensional conformal radiation therapy (3-D CRT), as well as IMRT. Newer equipment will give the physician and oncology team more options to treat patients, which will facilitate shorter treatment times, more accurate targeting of tumors, less side effects and better outcomes.

Please provide a general description of SRMC's oncology program. Suggested contents to help the Agency gain a better understanding of the service are as follows: (1) a description of the services of the oncology program such as radiation therapy, surgery and chemotherapy services; (2) a description of any specialized services (e.g., mammography screening, community education programs for cancer, etc.); (3) a description of any specialized equipment for diagnostic and/or treatment services; (4) a description of hospital/medical staff organizational structures for coordinating the activities of the oncology program, including information systems such as its tumor registry and tumor board; and (5) a description of SRMC's participation in any clinical investigative protocols through formal oncology network relationships with other providers.

Response:

SRMC is committed to continue the modernization and enhancement of its cancer diagnosis and treatment capabilities. For example, SRMC intends to submit a certificate of need application to initiate PET services at the Sumner Station location; this service does not currently exist in the market. Mammography and CT imaging are already at Sumner Station.

SRMC's cancer service has been accredited by the American College of Surgeons. In addition to radiation therapy and diagnostic services, SRMC provides an array of cancer support services including community education, pastoral care and nutrition services. Patient support groups are available through a partnership with Gilda's Club. Chemotherapy is provided in the community by Tennessee Oncology, the largest oncology group in the region, which participates in clinical trials through the Sarah C Cannon Center Cannon Center.

SRMC's Cancer Registry is a component of its cancer program designed for the collection, management, and analysis of data on all patients diagnosed and/or treated at with a malignancy or selected benign neoplasm. Reportable cases are identified through various case finding sources within the institution. Utilization of a computerized software system offers access to a broad range of data with various categories including demographics, cancer identification, stage, treatment, and diagnosis. The purpose of this data service is to provide accurate and complete cancer information while maintaining strict confidentiality of each patient record. The information is electronically stored for timely and accurate retrieval capabilities.

Under the leadership of the Cancer Committee as well as the Health Information Management (HIM) Department, the Cancer Registry at SRMC provides accurate, complete and timely collected data; assists and participates in cancer quality studies; and collaborates with physicians and other allied healthcare professionals in planning Cancer Conferences, professional education programs and community outreach programs.

The Cancer Registry also works closely with the Cancer Committee at large on monitoring compliance with American College of Surgeons (ACoS) Commission on Cancer Standards for our accreditation as a Community Hospital Cancer Program.

Information regarding the Tumor Board at SRMC and a summary of various cancer outreach activities as at Attachment 4.

Additional information regarding the organization of cancer services at SRMC is provided in response to question 14 below.

5. Section B, Project Description, Item II.E.

The response in the general remarks to the questions in this section is noted. One of these - the \$3,729,787 cost of the replacement linear accelerator unit appears to differ from the amounts in (a) the Project Costs Chart, line 7 - \$4,449,022.00 and (b) – the Varian Medical Systems equipment quote in Attachment B.II.E.2 – \$3,199,787.00. Please clarify.

Response: The cost of the linear accelerator unit without maintenance is \$3,199,787.00; with maintenance for 5 years the cost is \$3,729,787. The total amount of fixed equipment (\$4,449,022.00) includes fixed equipment items other than the linear accelerator, as described in the response to question 9 below.

Please note that the equipment quote expired on June 27, 2014. Please provide an addendum or updated quote from the equipment vendor such that the offer will be in effect on the date that the application will be heard by HSDA (November 2014 at earliest).

Response: Updated quote attached as Attachment 5.

For clinical applications, please provide brief definitions that correspond to the terms used in the narrative – IMRT, IGRT and SRS. It may be helpful to a better appreciation of the project to describe how these items contribute to the applicant's plans to provide modern cancer radiation therapy services.

Response: IMRT refers to Intensity Modulated Radiation Therapy; this mode of radiation therapy is available on the existing unit, but the replacement unit will be faster and offer enhanced precision. IGRT refers to Image Guided Radiation Therapy, and SRS refers to Stereotactic Radiosurgery. Additional discussion of these modalities is set forth in response to question 4 above.

6. Section C. Need Item 1. (State Health Plan and Project Specific Criteria – Construction, Renovation)

State Health Plan: The responses are noted. Please use the Exhibit at the end of this questionnaire to format the answers to the suggested questions that apply to each of the five general principles.

Response: The Exhibit has been completed as Attachment 6(A).

Project Criteria – Construction, Renovation:

Item 1.a. - Please comment on the relevance of existing licensure by the Department of Health as a consideration in relocating to the hospital's outpatient campus.

Response: The Sumer Station campus is licensed as part of SRMC, which facilitates the treatment of inpatients. As part of the hospital, the linear accelerator can provide

inpatient services without the necessity to admit the patient separately to the radiation therapy center, create a new patient record, etc. Licensing the facility as part of SRMC also facilitates staffing and management of the facility.

Item 1.b – The utilization for 2013 is identified as 4,033 treatments in the response. However, review of the hospital Joint Annual Report revealed 411 inpatient plus 3,927 outpatient treatments = 4,338 total treatments in 2013. Review of HSDA medical equipment records revealed 3,971 total treatments. Which amount is correct and why? Please explain.

Response: Upon careful rechecking of its data, SRMC has confirmed that the correct number for 2013 is 3,979, which is the amount reported to the Agency in SRMC's 2013 equipment survey. In the course of checking its data, SRMC also determined that the number of inpatient radiation treatments was misstated in its Joint Annual report; the correct number is 52 rather than 411. A corrected Joint Annual Report will be submitted to the Department of Health. Pages 12 and 14 of the application have been revised to include the correct number for 2013, and these pages are attached under Attachment 6(B).

7. Section C. Need, Item 4. B. (Service Area Demographics-Special Needs)

Based on a review of HSDA Equipment Registry records, it appears that residents of the 2-county service area accounted for approximately 3,617 linear accelerator treatments or 92% of SRMC's 3,927 total treatments in calendar year (CY) 2013. Additionally, it appears that residents of the service area also accounted for another 3,632 treatments at hospitals in Davidson County in CY2013 (see table in next question). Given this information, a better understanding of the prevalence of cancer in the service area would be appreciated. Please briefly summarize the cancer rate in the service area by referring to the Department of Health Cancer Registry for the most recent 3 consecutive year period available. In your response, it would help to include comparisons to statewide and national averages.

Response: Based on information in the report titled Cancer in Tennessee 2005-2009 published in 2013 by the Division of Policy, Planning and Assessment, Tennessee Department of Health, the following information is relevant:

- *For the period 2005-2009, Tennessee had the 16th highest cancer incidence rate in the country and the 6th highest cancer mortality rate.*
- *Tennessee's cancer incidence rate for the period was 476.8 per 100,000.*
- *Sumner County's cancer incidence rate for the period was 487.6 per 100,000, 2.3% higher than the Tennessee rate*
- *Macon County's cancer incidence rate for the period was 554 per 100,000, 16% higher than the Tennessee rate.*

Given that cancer occurs with more frequently in the service area than the statewide average, it is important that modern high-quality treatment resources be conveniently available.

Please also provide the linear accelerator treatments per 1,000 population for the service area and the State of Tennessee overall. Linear accelerator treatment data is available from Alecia Craighead at the HSDA offices.

Response: Based on information provided by Ms. Craighead, statewide use rate for linear accelerator treatments in 2013 was 48.662 treatments per 1,000 of population. The use rate in 2013 for Sumner County was 39.980 and the use rate for Macon County was 28.662. The lower use rates in Sumner and Macon counties suggest the potential for higher volumes in the future on SRMC's linear accelerator.

8. Section C, Need, Item 6

As the applicant is aware, the minimal linear accelerator utilization standard is 6,000 treatments per year. HSDA Equipment Registry records reflect that approximately 7,431 linear accelerator treatments were performed on service area residents at SRMC and other hospitals in Tennessee in 2013, with 49% being performed at SRMC.

Patient origin by county for calendar year 2013 is shown in the table below.

County	Treatments at SRMC - 2013	Treatments at Davidson County Hospitals	All other TN Hospitals	Total
Sumner	3,200	3,493	80	6,773
Macon	417	139	102	658
Total	3,617	3,632	182	7,431

Source: HSDA Equipment Registry, 2013 Service Utilization Records

Since the applicant is projecting 4,375 treatments in 2017 and 4,450 treatments in 2018, it appears that the applicant does not expect a significant increase in the service's market share to reach the State Health Plan's minimum capacity of 6,000 treatments per year. Please summarize the strategies being implemented by SRMC other than the proposed relocation of the service that might help SRMC reach the treatment standard at some point within 5 years following project completion in October, 2016.

Response: The planning for this project was based on conservative assumptions regarding growth in market share. SRMC is fully committed to the continued evolution and enhancement of cancer care in the community. As previously noted, SRMC intends to file an application to initiate PET services at Sumner Station. While SRMC hopes the elevation of the level of services available locally will decrease outmigration, SRMC believes it would be imprudent to project linear accelerator volumes reaching 6,000, an increase of almost 50%. In this regard, SRMC notes the minimum of 6,000 treatments in

the State Health Plan relates to a new linear accelerator service or additional linear accelerator capacity, not to the mere relocation of an existing service. The existing linear accelerator service is financially viable, the relocated service will be financially viable with the volumes projected, and the elimination of the service would result in significant hardship for a large number of patients.

What accounts for the 11.4% increase in utilization from 3,927 treatments in 2013 to 4,375 projected treatments in Year 1 of the project? Please justify the increase by showing a breakout of the projected volumes (inpatient and outpatient) and the methodology used to determine same.

Response: *A noted above, the total number of treatments in 2013 was 3,979. Year 1 of the project will be 2017, and the total number of treatments projected is 4,375, including 61 projected inpatient treatments, an increase in total volume of 10% in 4 years. The projected increase in volumes in 2017 is based on several factors: aging population and thus increased incidence of cancer; a reduction of outmigration due to better technology; and the likelihood that the lower linear accelerator use rates in Sumner and Macon counties will move toward the state average.*

9. Section C, Economic Feasibility Item 1 (Project Costs Chart)

The following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states "The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Is the \$4,449,022 fixed equipment cost listed in Line A.7 of the Project Cost Chart consistent with this Rule? In your response, please provide a breakout of the key cost items of the fixed unit that apply to the project. If not, please make the necessary equipment cost adjustments and submit a revised Project Cost Chart.

Response: *As explained above, Line A.7 includes all items of fixed equipment, not just the linear accelerator. Items of fixed equipment other than the linear accelerator are as follows:*

- *CT simulator - \$675,000*
- *Ceiling-mounted injector - \$44,235*

10. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

The page numbering referred to in Line D.9 (“Other Expenses”) of both the Historical and Projected Data Charts should be changed to reflect page 21 in lieu of page 23. Please make the changes and submit a replacement page for the charts.

Review of the Income Statement (YTD ending December 2013) in the attachments revealed differences from the Historical Data Chart (2013 column) for revenues & expenses such that net income appears to be understated by approximately \$4.4 million. Please clarify.

Response: In the course of responding to this question, SRMC determined that the Historical Data Chart in the Application had been erroneously prepared from an internal report that also included non-hospital operations. Attached under Attachment 10 are replacement pages 19, 20 and 21 that (1) correct the Historical Data Chart and (2) correct the references to page 23.

The difference in 2013 net operating income in the corrected Historical Data Chart (\$6,406,000) and net income in the 2013 financial statement (\$10,647,021) is attributable to the following:

- The Historical Data chart includes \$4,152,000 for federal income taxes that are not in the internal financial statement because FIT is paid at the parent level. SRMC elected to include federal taxes in the Historical Data Chart as a more accurate representation of SRMC’s financial results*
- The Historical Data Chart does not include a one-time positive adjustment to income from rent in the amount of \$1,843,000, which is included in the financial statement. This item was excluded from the Historical Data Chart because it was a one-time adjustment and excluding it is consistent with historical consistency.*
- The Historical Data Chart does not include interest as an expense, whereas the financial statement includes an interest expense allocation of \$1,754,000. SRMC elected not to include this allocation in the Historical Data Chart because it is not related to debt incurred by SRMC, but is an allocation of interest by the parent organization not reflective of financial results at SRMC.*

11. Section C., Economic Feasibility, Item 6 A. and 6 B.

Your response is noted. Please provide a comparison of the applicant facility’s proposed charges to the range of charges generated from the HSDA Equipment Registry found in the “Applicant’s Toolbox” on the HSDA website (www.tn.gov/hsda).

Response: The Applicant’s proposed average gross charge in 2017 is \$1,996. According the Agency’s Medical Equipment Registry data, in 2012 the median charge in the state was \$1,077.79 and the 3rd Quartile was \$1,406.21.

12. Section C., Economic Feasibility, Item 11 b.

The goals related to a more convenient and accessible site are noted. In 2013, area residents used several hospitals in Nashville with the highest use being Vanderbilt Medical Center (1,189 treatments), Skyline Medical Center (1,292 TX's) and St Thomas-Midtown (355 TX's). Looking at distance/travel times as a key factor, what are the savings in mileage/driving times to the proposed outpatient campus that residents of the service area could expect?

Response: The mileage and approximate driving time from Sumner Station to each of the 3 locations are as follows:

<i>Sumner Station to</i>	<i>Distance (mile)</i>	<i>Drive Time (1 way)</i>
<i>Skyline</i>	<i>17.3</i>	<i>22 min.</i>
<i>St. Thomas-Midtown</i>	<i>26.7</i>	<i>28 min.</i>
<i>Vanderbilt</i>	<i>27</i>	<i>28 min.</i>

Assuming an average of 25 treatments per patient, a patient would drive between 865 to 1,350 miles during the course of treatment in order to access services at one of the 3 sites in Davidson County. Total driving time in the course of treatment would range from 18.3 hours to 28 hours. The additional burden on patients to receive treatment in Nashville is obvious.

What other key benefits should residents and their attending physicians be aware of in selecting SRMC's service in lieu of other sites outside the service area?

Response: *In addition to avoiding the time, physical toll and expense of travel for multiple radiation therapy treatments, residents who receive treatment at Sumner Station will be much closer to the other components of cancer care in the community, including diagnostic services, chemotherapy, nutritional services, pastoral care, and support groups.*

13. Section C., Contribution to Orderly Development, Item 1

Your response is noted. Other than managed care organizations, please list health care providers or organizations the applicant has or plans to have contractual and/or working agreements with.

Response: *See the list attached as Attachment 13.*

14. Section C., Contribution to Orderly Development, Item 4

With respect to professional staff, please discuss the clinical leadership of the service and provide a CV of the medical director, if applicable. How many and what types of

subspecialty physicians participate in the delivery of cancer services to SRMC's patients and/or development of new clinical knowledge?

Response:

The CV of the Medical Director is attached as Attachment 14.

Cancer care at SRMC is under the leadership of its cancer committee. The cancer committee is responsible for goal setting, planning, initiating, implementing, evaluating, and improving all cancer-related activities. The care of the cancer patients requires a multidisciplinary approach and encompasses numerous physician and non-physician professionals. Required physician members are a diagnostic radiologist, pathologist, general surgeon, medical oncologist, and radiation oncologist. Required non-physician members include the program administrator, oncology nurse, social worker or case manager, certified tumor registrar (CTR), performance improvement or quality management professional. Additional physician or non-physician cancer committee members are required for specific categories, such as a hospice/home care nurse or administrator, pain control/palliative care physician specialist and cancer clinical research data manager or nurse. Additional members of the committee from time to time may include individuals from various disciplines such as dietary, pharmacy, pastoral care, mental health, or the American Cancer Society.

The number and types of physicians on staff at SRMC involved in cancer care are as follows:

- *Radiation oncologist – 1 active staff; 10 coverage staff*
- *Medical oncologist – 2 active staff; 16 consulting/coverage staff*
- *General Surgeons – 4 active staff*
- *Urologists – 4 active staff*
- *Radiologists – 9 active staff*
- *Pathologists – 4 active staff*

15. Section C., Contribution to Orderly Development, Items 7 and 9

The copy of SRMC's licensure survey dated October 11, 2006 is noted. Absent any more recent survey, please provide a copy of the approved plan of correction for the 10/2006 survey by the Department of Health.

Response: *The plan of correction is included in the letter from Bruce James to Nina Monroe dated October 24, 2008, that was included with original application.*

The hospital license submitted with the application expired on June 25, 2014. Please provide a copy of the current license.

Response: *A copy of the current license is included as part of Attachment 15.*

Please also provide a copy of the Joint Commission's accreditation certificate along with the most recent Joint Commission's Survey Report and the facility's response.

Response: A copy of the Joint Commission accreditation and survey information is included as part of Attachment 15.

16. Progress Update

According to HSDA records, LifePoint Hospitals has ownership in the following approved, but unimplemented Certificate of Need projects:

Starr Regional Medical Center, CN1404-009A
Sothern Tennessee Medical Center, CN1402-005A

Please provide a brief two-three sentence update regarding the progress made to date, and where the project stands in relationship to its projected schedule and estimated cost.

Response: The project at Southern Tennessee Medical Center to implement mobile PET service (CN1402-005A) has been implemented. The project at Starr Regional Medical Center (CN1404-009A) was approved in July of this year and construction is not yet underway.

Very truly yours,

BUTLER SNOW LLP



Dan H. Elrod

clw
Attachments

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DavidsonNAME OF FACILITY: Sumner Regional Medical Center

I, Don H Ehl, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

[Signature]
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 26 day of August, 2014, witness my hand at office in the County of Davidson, State of Tennessee.

Melisa Ann Raines
NOTARY PUBLIC

My commission expires June 21, 2016.

HF-0043

Revised 7/02



My Comm. Expires
June 21, 2016

Attachment 2

August 26, 2014

11:58am

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:25 PM 05/19/2010
FILED 04:11 PM 05/19/2010
SRV 100536424 - 4825590 FILE

**Certificate of Formation
of
Sumner Regional Medical Center, LLC**

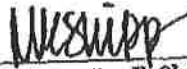
The undersigned, an authorized natural person, for the purpose of forming a limited liability company, under the provisions and subject to the requirements of the State of Delaware, particularly Chapter 18, Title 6 of the Delaware Code and the acts amendatory thereof and supplemental thereto, and known, identified, and referred to as the Delaware Limited Liability Company Act (the "Act"), hereby certifies that:

FIRST: The name of the limited liability company is Sumner Regional Medical Center, LLC (the "Company").

SECOND: The address of the registered office and the name and address of the registered agent of the Company required to be maintained by Section 18-104 of the Act is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation as of May 19, 2010.

By: _____



Mary Kim E. Shipp
Authorized Person

LifePoint Hospitals in Tennessee

Livingston Regional Hospital
315 Oak Street
Livingston, TN 38570

Riverview Regional Medical Center
158 Hospital Dr
Carthage, TN 37030

Southern Tennessee Regional Healthy System at Lawrenceburg
1607 South Locust Ave
Lawrenceburg, TN 38464

Southern Tennessee Regional Health System at Sewanee
1260 University Ave
Sewanee, TN 37375

Southern Tennessee Regional Health System at Pulaski
1265 East College Street
Pulaski, TN 38478

Southern Tennessee Regional Health System at Winchester
185 Hospital Rd
Winchester, TN 37398

Starr Regional Medical Center
1114 West Madison Ave
Athens, TN 37303

Starr Regional Medical
886 Highway 411 North
Etowah, TN 37331

Sumner Regional Medical Center
555 Hartsville Pike
Gallatin, TN 37066

Trousdale Medical Center
500 Church Street
Hartsville, TN 37074

Attachment 4

Sumner Regional Medical Center Cancer Program

TITLE: CANCER CONFERENCE (Tumor Board)

POLICY: To provide routine multidisciplinary collaboration between clinicians for the purpose of providing comprehensive management for the oncology patient.

Sumner Regional Medical Center's Cancer Committee has approved cancer conferences to be held monthly. Cancer Conferences are integral to improving the care of cancer patients by contributing to the patient management process and outcomes and providing education to physicians and other staff in attendance.

Conference is available to all medical staff personnel and Allied Health personnel. Required attendance at conference is physicians responsible for the site being presented along with medical and radiation oncology, radiology, pathology, surgery and medicine.

PROCEDURE:

- The managing physician selects cases based on clinical importance from cases currently being managed. Case presentations include patients recently seen in consultation as well as patients being actively managed as an inpatient or on an outpatient basis.
- Cancer Registry personnel are responsible for coordinating and maintaining cancer conference documentation. Cancer conferences are scheduled in advance. A yearly calendar of scheduled conference dates is to be completed by the end of November as well as reserving meeting room.
- The number of cases discussed is proportional (15 % of annual analytic caseload)
- 15% of our annual analytic case load will be presented at cancer conference with 75% of these cases being prospectively.
- Discussion will include:
 1. Review of clinical evaluation, i.e., diagnostic imaging studies and pathology
 2. Appropriate case management based on clinical presentation and extent of patient's disease, performance status, and co-morbidity
 3. Accurate AJCC stage (either clinical stage or working stage) or other appropriate stage
 4. National Comprehensive Cancer Center Network (NCCN) treatment guidelines or other treatment guidelines developed by nationally recognized organizations, such as the American Cancer Society of Clinical Oncology (ASCO), should be considered when discussing treatment options where appropriate.
 5. 90% of all Physicians required to attend must meet this percentage. Medical Oncology, Radiation Oncology, Radiology, Pathology, Surgery and Cancer Registry.
 6. A conference grid is maintained by the Cancer Registry to accurately monitor conference frequency (monthly), multidisciplinary attendance, total case presentation, the rate of prospective cases presentation, Options for clinical trial participation.

7. Conference grid includes documentation of the fact that AJCC staging or other appropriate staging was discussed, where appropriate.
8. Cancer Conference activities are reported by the Cancer Conference Coordinator to the Cancer Committee at least quarterly.

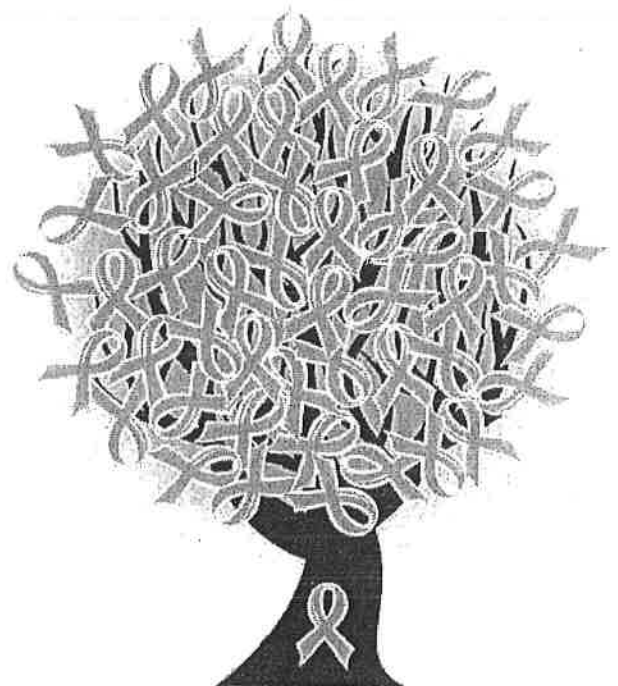
Conference documentation includes:

1. Date of meeting
2. Sites discussed/Prospective-retrospective
3. Physician attendance
4. Non-physician attendance
5. Clinical Staging and National Treatment guidelines reviewed and care plan consistent with guidelines
6. Eligible for clinical trials
7. Agenda for Cancer Conference provided to physicians

DISTRIBUTION: Cancer Program
APPROVAL: Cancer Committee
REVIEWED: 01/03; 01/05; 01/06; 02/07, 2/08, 2/10,2/14
REVISED: 1/04, 01/09
ORIGINAL: 2002

2013

2013 Outreach Summary



Sumner Regional Cancer Center at SRMC is committed to meeting the needs of our community and demonstrates this dedication by providing free cancer screenings and educational opportunities when available. In 2013, SRMC along with HighPoint Health System provided a breast cancer screening event with 28 people being screened. In addition, over 3000 people were reached at 5 educational events where cancer information was shared.

Gallatin Relay for Life – 5/9/2013

RRMC Breast Cancer Screening Event – 10/12/13

Gallatin Main Street Festival-10/5/2013

Vol State Latino Festival- 10/19/2013

Hank Thompson Trek or Treat 5K/United Against Lung Cancer Event-10/2013

ServPro Industries Employee Wellness Fair—10/18/2013

ABC Technologies/ABC Fuel Group/ Salga Plastic Breast Cancer Awareness Event- 10/17/2013

Breast Cancer Awareness Wellness Event- 10/17/2013

Imaging for Women at Sumner Station- October- November 2013 will provide screening mammography for the special price of \$75, which includes the exam and radiologist's interpretation.

5K Dash for Dottie- November 2, 2013- Fundraising event to honor a former SRMC employee whose life was cut short by breast cancer.

HighPoint Hospice @ SRMC- Grief Support 5 Week Class/Group- November 19-December 17, 2013

Attachment 6(A)

Exhibit 1 - Section C, Need, Item 1 (State Health Plan)

Please discuss how the proposed project will relate to the 5 Principles for Achieving Better Health of the State Health Plan. Each Principle is listed below with example questions to help the applicant in its thinking.

1. The purpose of the State Health Plan is to improve the health of Tennesseans.
 - a. How will this proposal protect, promote, and improve the health of Tennesseans over time?
 - b. What health outcomes will be impacted and how will the applicant measure improvement in health outcomes?
 - c. How does the applicant intend to act upon available data to measure its contribution to improving health outcomes?

Response: This project will promote the healing of cancer patients in the community by making state-of-the-art radiation therapy available at a convenient location that will be more accessible than the existing service. The project will also reduce the stress on sick patients by making it easier to access care.

2. Every citizen should have reasonable access to health care.
 - a. How will this proposal improve access to health care? You may want to consider geographic, insurance, use of technology, and disparity issues (including income disparity), among others.
 - b. How will this proposal improve information provided to patients and referring physicians?
 - c. How does the applicant work to improve health literacy among its patient population, including communications between patients and providers?

Response: The outpatient radiation therapy center will be available to all patients. SRMC is contracted with all existing TennCare MCOs in the area, and SRMC intends to continue its participation in all TennCare MCOs when the new MCO contracts are implemented in 2015.

3. The State's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the State's health care system.
 - a. How will this proposal lower the cost of health care?
 - b. How will this proposal encourage economic efficiencies?
 - c. What information will be made available to the community that will encourage a competitive market for health care services?

Response: This project achieves economic efficiency because it makes use of an existing building on an existing outpatient campus in order to provide the benefits of enhanced convenience and accessibility for cancer patients. The project will not result in any increase in patient charges or require additional staffing.

4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
 - a. How will this proposal help health care providers adhere to professional standards?
 - b. How will this proposal encourage continued improvement in the quality of care provided by the health care workforce?

Response: The project contributes to quality of care by replacing a linear accelerator that is at the end of its useful life with a state-of-the-art unit that assures the stability and availability of high quality radiation therapy treatment for many years to come. SMRC's commitment to quality care is evidenced by its designation by the Joint Commission as a Top Performer in Key Quality Measures.

5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.*
 - a. How will this proposal provide employment opportunities for the health care workforce?
 - b. How will this proposal complement the existing Service Area workforce?

Response: This project will not require any additional staffing and thus will not have an effect on the health care workforce.

Attachment 10

Attachment 13



My Custom Report

Contract Number	Contract Type	Contracting Entity	Department	Effective Date	Expiration Date	Responsible Party, Primary	Vendor Other Party
<u>66588.12267C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	3/16/1999	03/15/2015	Melton, Anne	Hendersonville Nursing Home, LTD.
<u>66588.12270C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	3/29/2010	03/28/2015	Melton, Anne	RAI Care Centers of Gallatin I, LLC
<u>66588.12272C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Cardiology	7/30/2009	07/31/2016	Melton, Anne	Centennial Medical Center
<u>66588.12274C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	12/20/1993	12/19/2014	Melton, Anne	NHC of Hendersonville
<u>66588.12282C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	1/9/1995	01/08/2015	Melton, Anne	Royal Care of Westmoreland
<u>66588.12285C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	6/1/2007	05/31/2015	Melton, Anne	Golden Living
<u>66588.12288C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	12/20/1993	12/19/2014	Melton, Anne	Hartsville Convalescent Center
<u>66588.12298C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	1/30/1998	01/29/2015	Melton, Anne	LifeTrust America, Inc
<u>66588.12303C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	9/1/1999	08/31/2014	Melton, Anne	Madison Healthcare and Rehabilitation Center
<u>66588.12310C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	9/27/1994	09/26/2014	Melton, Anne	Middle Tennessee Rehab at Sumner
<u>66588.12313C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	12/20/1993	12/19/2014	Melton, Anne	Gallatin Health Care Associates
<u>66588.12315C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	9/1/2006	08/31/2014	Melton, Anne	Patient Partners Surgery Center
<u>66588.12316C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	11/21/1993	11/20/2014	Melton, Anne	Highland Manor
<u>66588.12328C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	2/1/2000	01/31/2015	Melton, Anne	Vanderbilt Children's Hospital
<u>66588.12331C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	10/18/1999	06/25/2015	Melton, Anne	Summit Medical Center
<u>66588.12334C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	5/1/2011	04/30/2015	Melton, Anne	Saint Thomas Hospital
<u>66588.12370C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	11/7/2011	11/06/2014	Melton, Anne	Riverview Regional Medical Center South
<u>66588.12378C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	10/26/1999	10/25/2014	Melton, Anne	Green Surgery Center, LLC

No. Of Contract:

133

SUPPLEMENTAL- # 1

August 26, 2014

11:58am

Attachment 14

Robert T. McClure, M.D.

*1279 Twelve Stones Crossing
Goodlettsville, TN 37072
Home Phone: 615 855-0764
Work Phone: 615 328-6180
Cell Phone: 615 319-8478
Email: rtmccclure14@comcast.net*

Biographical Data

Date of Birth: 12/12/66

Place of Birth: Cincinnati, Ohio

Marital Status: Married to Joan

Children: Holly Marie, born 1/25/99

Olivia Anne, born 2/16/01

Education

Residency

*University of Cincinnati Hospital
Division of Radiation Oncology
Cincinnati, Ohio, 7/92-6/95
Chief Resident 7/94-6/95*

Internship

*The Christ Hospital
Internal Medicine
Cincinnati, Ohio, 7/91-6/92*

Medical School

*University of Cincinnati
College of Medicine
Cincinnati, Ohio, 1987-1991
Doctor of Medicine, 6/91*

College

*Xavier University
Cincinnati, Ohio, 1983-1987
B.S. Natural Sciences Major, 5/87
Scholars Program, 3.71 G.P.A.
Cum Laude*

High School

*Covington Latin
Covington, Kentucky, 1979-1983
Graduated 6 out of 41*

Robert T. McClure, M.D.***Specialized
Experience***

*3-D Conformal Therapy
Linac Based Stereotactic Radiosurgery
Intensity Modulated Radiation Therapy
Total Skin Electron Therapy
Microwave and Ultrasound Hyperthermia
Pediatric Oncology
Superficial Therapy
Brachytherapy
 gynecologic: interstitial/intracavitary
 prostate: transrectal ultrasound guided seed
 head and neck interstitial
 brain: permanent seed and interstitial
 intercolloidal P-32
I.V. SR-89 and P-32
I-131 for Thyroid Cancer*

Employment

*Tennessee Oncology, Full Partner
Nashville, TN 1/1/08-present
(Partners of Radiation Oncology Associates merged
With Tennessee Oncology)*

*Radiation Oncology Associates
Nashville, TN, 10/18/99-12/31/07
Full partner since 10/02*

*Cancer Care Specialists of Central Illinois,
Decatur, IL, 5/1/96-10/1/99*

*Employed in Radiation Oncology,
Central Florida, 7/1/95-4/15/96*

Research

*"Transient Elevation of PSA During Radiation
Therapy"
Presented at the Ohio State Radiologic Society
Annual Meeting on 5/7/94*

*Investigator with Central Illinois
Community Clinical Oncology Program
for SWOG, NSABP, GOG, RTOG, MDACC
Protocols
Principal reviewer for all radiation protocols
at monthly Treatment Protocol Committee Meeting*

Robert T. McClure, M.D.

Honors/Awards

*Hunnicutt Award from the Department of
Family Medicine, 1990
Alpha Sigma Nu National Jesuit Honors Society
Inducted 5/87
Dean's list 8 consecutive semesters, Xavier Univ.
Lettered in Men's Varsity Tennis, Xavier Univ.
1983-1987
Captain, 1986-1987
Trustee Scholarship, Xavier Univ., 1983-1987.*

Professional

*Member, American Society for Therapeutic
Radiology and Oncology
Member and Treasurer, Sumner County Medical Society,
2001
Chairman, Sumner Regional Hospital Cancer Committee,
2002-present; started first monthly Tumor Conferences at
SRMC, and served as Cancer Liaison Physician 2002-
2005;
Guided the Cancer Program to approval by the American
College of Surgeons Commission on Cancer, 3 Year
Approval with Commendation, 2006, 2009, & 2012
Chairman, Sumner Regional Hospital Diagnostic Medicine
Department, 2002 and 2006
Member of Sumner Regional Hospital Quality Committee,
2002-present*

Certification

*Diplomat of the American Board of Radiology, 6/96,
Active participant in MOC program
Passed recertification exam 9/03 and 4/14
State of Tennessee Medical License, Active
State of Ohio Medical License, Active
State of Florida Medical License, Inactive*

References

Available upon request

Attachment 15

Sumner Regional Medical Center
Gallatin, TN

has been Accredited by



The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Hospital Accreditation Program

September 15, 2012

Accreditation is customarily valid for up to 36 months.

Isabel V. Hoverman, MD, MACP
Chair, Board of Commissioners

Organization ID #: 7832
Print/Reprint Date: 01/08/13

Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit, national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.



This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission. Please consult Quality Check on The Joint Commission's website to confirm the organization's current accreditation status and for a listing of the organization's locations of care.

Standard	Standard Text	Total EPs	Addressed 45 Day EPs	Chapter Owner
MM.04.01.01	Medication orders are clear and accurate.	1	0	
NPSG.03.04.01	Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. Note: Medication containers include syringes, medicine cups, and basins.	1	0	Tommy Cothron
UP.01.03.01	A time-out is performed before the procedure.	1	0	Becky Grant
ESC 60 Day				
Standard	Standard Text	Total EPs	Addressed 60 Day EPs	Chapter Owner
EC.02.05.09	The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.	1	0	
LS.02.01.20	The hospital maintains the integrity of the means of egress.	1	0	Mike Messer
LS.02.01.35	The hospital provides and maintains systems for extinguishing fires.	1	0	Mike Messer
MM.03.01.01	The hospital safely stores medications.	1	0	Tommy Cothron
MS.08.01.03	Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to revoke an existing privilege prior to or at the time of renewal.	1	0	
PC.01.02.03	The hospital assesses and reassesses the patient and his or her condition according to defined time frames.	1	0	Stacey Crudup/Tammy Carter
PC.01.03.01	The hospital plans the patient's care.	1	0	Anne Melton/Penny Clark
PC.03.05.03	For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital uses restraint or seclusion safely.	1	0	Anne Melton/Penny Clark
RC.01.01.01	The hospital maintains complete and accurate medical records for each individual patient.	1	0	Jon Koederitz
RC.02.03.07	Qualified staff receive and record verbal orders.	1	0	Jon Koederitz

Sumner Regional Medical Center
Organization ID: 7832
555 Hartsville PikeGallatin, TN 37066

Accreditation Activity - Measure of Success Form
Due Date: 4/4/2013

HAP Standard MM.04.01.01 Medication orders are clear and accurate.

Elements of Performance:

13. The hospital implements its policies for medication orders.

Scoring C
Category:

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual
Goal (%): 94

Month 2 Date: 12/2012

Month 2 Actual
Goal (%): 95

Month 3 Date: 01/2013

Month 3 Actual
Goal (%): 98

Month 4 Date: 02/2013

Month 4 Actual
Goal (%): 97

Actual Average
Goal (%): 96

Optional
Comments:

HAP Standard PC.01.02.03 The hospital assesses and reassesses the patient and his or her condition according to defined time frames.

Elements of Performance:

5. For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a

procedure requiring anesthesia services. (See also MS.03.01.01, EP 8; RC.02.01.03, EP 3)

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 97

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 98

Month 3 Date: 01/2013

Month 3 Actual Goal (%): 94

Month 4 Date: 02/2013

Month 4 Actual Goal (%): 94

Actual Average Goal (%): 96

Optional Comments:

HAP Standard PC.03.05.03 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital uses restraint or seclusion safely.

Elements of Performance:

2. For hospitals that use Joint Commission accreditation for deemed status purposes: The use of restraint and seclusion is in accordance with a written modification to the patient's plan of care.

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 84

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 100

Month 3 Date: 01/2013

Month 3 Actual Goal (%): 100

Month 4 Date: 02/2013

Month 4 Actual Goal (%): 100

Actual Average Goal (%): 96

Optional Comments:

HAP Standard UP.01.03.01 A time-out is performed before the procedure.

Elements of Performance:

5. Document the completion of the time-out. Note: The hospital determines the amount and type of

documentation.

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 95

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 98

Month 3 Date: 01/2012

Month 3 Actual Goal (%): 99

Month 4 Date: 2/2012

Month 4 Actual Goal (%): 98

Actual Average Goal (%): 97

Optional Comments:

SUPPLEMENTAL
#2

August 28, 2014

VIA HAND DELIVERY

Jeff Grimm
HSDA Examiner
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Certificate of Need Application CN1408-036
Sumner Regional Medical Center – Relocation of
Linear Accelerator from Main Hospital Campus to Outpatient Campus

Dear Mr. Grimm:

Responses to the questions in your letter dated August 27, 2014, are below. Please let us know if you need additional information.

1. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

The revised charts are noted based on reasons explained following comparison to the financial statements in the application. However, it appears that the net operating revenue of \$114,011,000 in the revised Historical Data Chart is approximately \$23,765,790 lower than the \$137,776,789 net revenue reported in the hospital's 2013 Joint Annual Report. Please explain the reason(s) for the difference between these amounts for the 2013 reporting period.

Response: The principal reason for the difference is because the Joint Annual Report net revenue number is not adjusted for bad debt in the amount of \$24,538,000, whereas the net operating revenue number in the Historical Data Chart is adjusted for bad debt. Any other differences are attributable to the Historical Data Chart having been prepared from internal reports that use accrued rather than actual deductions.

*The Pinnacle at Symphony Place
150 3rd Avenue South, Suite 1600
Nashville, TN 37201*

DAN H. ELROD
615.651.6702
dan.elrod@butlersnow.com

T 615.651.6700
F 615.651.6701
www.butlersnow.com

2. Section C., Economic Feasibility, Item 6 A. and 6 B.

The comparison of the average gross charge in 2017 to the HSDA range of charges for similar projects is noted.

In reviewing the revised Projected Data Charge, it appears that the average gross charge increases by approximately 15% from \$1996 per treatment in Year 1 to \$2290 per treatment in Year 2. What accounts for the increase to this extent? Please clarify.

Response: Year 2 in the Projected Data Chart was incorrectly completed. SRMC does not intend to change charges from 2017 to 2018. A second revised page 20 is enclosed.

3. Section C., Economic Feasibility, Item 8

The response in the application indicates that projected Medicare and TennCare gross revenues account for approximately 28.4% and 6.6%, respectively, of total gross revenues in Year 1 of the project. Compared to the 2013 JAR, the hospital's mix as a percentage of total hospital gross revenue was approximately 50.3% Medicare and 14% TennCare in 2013. As a result, the radiation therapy service appears to have significantly lower Medicare/TennCare mix than the hospital as a whole. Please address by identifying the reasons for same.

Response: The Medicare percentage stated in the application included only traditional Medicare, whereas the Joint Annual Report classified both traditional Medicare and Medicare Advantage in the Medicare category. If Medicare Advantage is included in SRMC's payor mix for radiation therapy service, the total Medicare percentage is 45.16%. The lower TennCare percentage for radiation therapy is understandable, because the whole hospital payor mix includes services, such as obstetrical services, that have a very high TennCare payor mix.

Very truly yours,

BUTLER SNOW LLP



Dan H. Elrod

clw

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DavidsonNAME OF FACILITY: Sumner Regional Mental Center

I, Dan H. Elrod, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

[Signature]
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 28th day of August, 2014,
witness my hand at office in the County of Davidson, State of Tennessee.

Melisa Ann Raines
NOTARY PUBLIC

My commission expires 6-21, 16.

HF-0043

Revised 7/02



My Comm. Expires
June 21, 2016



State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in The Tennessean which is a newspaper
(Name of Newspaper)
of general circulation in Sumner, Tennessee, on or before August 10, 20 14,
(County) (Month / day) (Year)
for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Sumner Regional Medical Center, an existing hospital
(Name of Applicant) (Facility Type-Existing)

with an ownership type of limited liability company intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: relocation of linear accelerator services to its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard, Gallatin, TN, and to initiate linear accelerator services at that location. An existing linear accelerator will be replaced as part of the project. The project will require build-out of approximately 9,150 sq. ft. of existing space and 1,570 sq. ft. of new construction. The total project cost is approximately \$10,512,421. The project does not involve a change in licensed bed capacity or the initiation of any service requiring a certificate of need, except the relocated linear accelerator service.

The anticipated date of filing the application is: August 15, 20 14

The contact person for this project is Dan Elrod Attorney
(Contact Name) (Title)

who may be reached at: Butler Snow LLP 150 3rd Avenue South, Suite 1600
(Company Name) (Address)

Nashville TN 37201 615 / 651-6702
(City) (State) (Zip Code) (Area Code / Phone Number)

[Signature] 8/8/2014 dan.elrod@butlersnow.com
(Signature) (Date) (E-mail Address)

The Letter of Intent must be **filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:**

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954**

DATE: October 31, 2014

APPLICANT: Sumner Regional Medical Center
225 Big Station Camp Boulevard
Gallatin, Tennessee 37066

CN1408-036

CONTACT PERSON: Dan Elrod, Esquire
150 3rd Avenue South, Suite 1600
Nashville, Tennessee 37201

COST: \$10, 512,421

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Sumner Regional Medical Center (SRMC), seeks Certificated of Need (CON) approval for the relocation of linear accelerator services to its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard, Gallatin, Tennessee, and the initiation of linear accelerator services at said location. An existing linear accelerator will be replaced as part of the project. The project does not involve a change in licensed bed capacity or the initiation of any service requiring a CON, except relocation of the linear accelerator service.

The project will require the build out of approximately 9,150 square feet of existing space and 1,570 square feet of new construction. The construction costs for this project are projected to be \$260 per square foot for renovation, \$741.60 per square foot for new construction, and \$330.50 per square foot combined. HSDA 2011-2013 construction costs for hospitals in the 3rd quartile were \$249 per square foot, \$324 per square foot for new construction, and \$274.63 per square foot for combined. The applicant notes the new construction was for the vault of the linear accelerator, which is very expensive due to the required shielding.

Sumner Regional Medical Center is a 155 bed acute care hospital and is 100% owned by LifePoint Hospitals. LifePoint Hospitals, Inc. is headquartered in Brentwood, Tennessee. LifePoint operates 63 hospitals in 20 States, including 10 in Tennessee.

The total estimated project cost is \$10,512,421 and will be funded through cash reserves as documented by the Chief Financial Officer in Attachment C, Economic Feasibility 2.

This application has been placed on the Consent Calendar. Tenn. Code Ann. § 68-11-1608 Section (d) states the executive director of Health Services and Development Agency may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The applicant's service area is Macon and Sumner counties.

County	2014 Population	2018 Population	% of Increase/ (Decrease)
Macon	23,188	24,121	4.0%
Sumner	172,262	183,406	6.5%
Total	195,450	207,527	6.2%

Tennessee Department of Health, Division of Policy, Planning, and Assessment-Office of Health Statistics, 2020,
June 2013, Revision

Sumner Regional Medical Center is the only provider of radiation therapy in the two service area counties. The historic and projected utilization for radiation procedures is illustrated below.

Sumner Regional Medical Center	2011	2012	2013	Year 1	Year 2
	4,038	4,043	3,979	4,375	4,450

HSDA Equipment Registry

The applicant's stated need for the project is to provide outpatient radiation therapy patients easier access to the service. The existing linear accelerator that has been in service since 1996 will be replaced. This linear accelerator is considered replacement equipment and is not considered as major medical equipment. The replacement unit will be a Varian TrueBeam unit with CT simulator. The unit is capable of conventional radiation therapy and IMRT, IGRT, and SRS. SRMC is committed to the modernization and enhancement of cancer diagnosis and treatment capabilities. SRMC intends to submit a CON application for PET services at Station Camp. PET services are not currently provided in the service area.

The outpatient campus at Sumner Station is located in an existing building located off Vietnam Veterans Parkway with easy access, improved parking, and a canopied entrance. This project will also facilitate the needed replacement of SRMC's linear accelerator with a new state-of-the-art unit that assures continuation of modern radiation therapy services in the community.

TENNCARE/MEDICARE ACCESS:

The applicant will participate in the TennCare and Medicare programs. The applicant is contracted with all TennCare plans that operate in Middle Tennessee. SMRC's projected gross revenues for radiation therapy from TennCare/Medicaid in year 1 are \$578,932 and gross Medicare revenues are projected to be \$2,480,761.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine they are mathematically accurate and the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located on page 16 of the application. The total project cost is \$10,512,421.

Historical Data Chart: The Historical Data Chart is located in Supplement of the application. The applicant reported 14,330, 15,146, and 15,967 admissions in 2011, 2012,

and 2013, respectively. The applicant reported net operating revenues of \$4,941,000, \$4,304,000, and \$6,406,000 each year, respectively.

Projected Data Chart: The Projected Data Chart is located in Supplemental 2. The applicant projects 4,375 and 4,450 treatments in years one and two, respectively. The total net operating revenue in year one is projected to be \$516,000 and \$648,000 in year two of the project.

The applicant's projected average gross charge in 2017 is \$1,996. The HSDA equipment registry 2012 median charge was \$1,077.79 and the 3rd quartile charge was \$1,406.21.

SRMC already owns the building at Sumner Station, and out-patient services and medical offices are located on site. In addition, any alternative project would not be as cost effective. This project best accomplishes the goal to provide radiation therapy services in a more convenient and accessible setting.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

The applicant provides a listing of managed care contracts and health providers or organizations in Attachment C, Contribution to Orderly Development and Attachment 13 of Supplemental 1, respectively.

The project should have only positive effects on the healthcare system due to improved patient convenience. The updated linear accelerator service will enhance treatment for Macon and Sumner County residents by providing state-of-the-art treatment in their community. SRMC is the only provider in the service area.

The current and proposed staffing for the radiation therapy service includes 1.0 FTE dosimetrist, 2.7 FTE radiation therapy technologists, and 1.0 FTE registered nurse. The physicians who are involved with cancer care at SRMC include 1 radiation oncologist, with 10 covering; 2 medical oncologists with 16 covering, 4 general surgeons, 9 radiologists, and 4 pathologists.

SRMC is accredited by the Joint Commission and licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities. The cancer program is accredited by the American College of Surgeons Commission of Cancer Care. The most recent licensure survey and the plan of correction are included in Attachment C, Orderly Development of Healthcare-7(d).

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

CONSTRUCTION, RENOVATION, EXPANSION, AND REPLACEMENT OF HEALTH CARE INSTITUTIONS

1. Any project that includes the addition of beds, services, or medical equipment will be reviewed under the standards for those specific activities.

This criterion is not applicable.

2. For relocation or replacement of an existing licensed health care institution:
 - a. The applicant should provide plans which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.

SRMC did not develop any plans for renovation because the major goal of the project was to relocate the radiation therapy away from the main campus for convenience and accessibly. No alternatives were considered as the Sumner Station location already exists and is cost effective.

- b. The applicant should demonstrate that there is an acceptable existing or projected future demand for the proposed project.

The existing service is well utilized.

Sumner Regional Medical Center	2011	2012	2013	Year 1	Year 2
	4,038	4,043	3,979	4,375	4,450

HSDA Equipment Registry

- 3. For renovation or expansions of an existing licensed health care institution:
 - a. The applicant should demonstrate that there is an acceptable existing demand for the proposed project.
 - b. The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion.

The above criteria are not applicable.